US009554851B2

(12) **United States Patent**
Sklar et al.

(10) **Patent No.: US 9,554,851 B2**
(45) **Date of Patent: Jan. 31, 2017**

(54) **SYSTEM AND METHOD FOR ADVANCING, ORIENTING, AND IMMOBILIZING ON INTERNAL BODY TISSUE A CATHETER OR OTHER THERAPEUTIC DEVICE**

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(72) Inventors: **Martin J. Sklar**, Needham, MA (US); **Howard Ring**, Newton, MA (US)

(73) Assignee: **ABLACOR MEDICAL CORPORATION**, Needham, MA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 258 days.

(21) Appl. No.: **13/934,351**

(22) Filed: **Jul. 3, 2013**

(65) **Prior Publication Data**

US 2013/0317385 A1 Nov. 28, 2013

Related U.S. Application Data

(63) Continuation of application No. 11/694,002, filed on Mar. 30, 2007, now Pat. No. 8,535,304.
(Continued)

(51) **Int. Cl.**

A61B 18/18	(2006.01)
A61M 25/01	(2006.01)
A61B 5/053	(2006.01)
A61B 5/00	(2006.01)
A61B 18/14	(2006.01)

(Continued)

(52) **U.S. Cl.**
CPC ***A61B 18/18*** (2013.01); ***A61B 5/053*** (2013.01); ***A61B 5/4836*** (2013.01); ***A61B 18/1492*** (2013.01); ***A61B 34/71*** (2016.02); ***A61B 34/72*** (2016.02); ***A61M 25/0113*** (2013.01); ***A61B 18/1815*** (2013.01); ***A61B 2017/003*** (2013.01); ***A61B 2018/00291*** (2013.01); ***A61B 2018/1861*** (2013.01); ***A61M 25/0147*** (2013.01);
(Continued)

(58) **Field of Classification Search**
CPC . A61B 18/18; A61B 18/1492; A61B 18/1815; A61B 2018/00291; A61B 2018/1861; A61B 2019/2242; A61B 2019/2249
See application file for complete search history.

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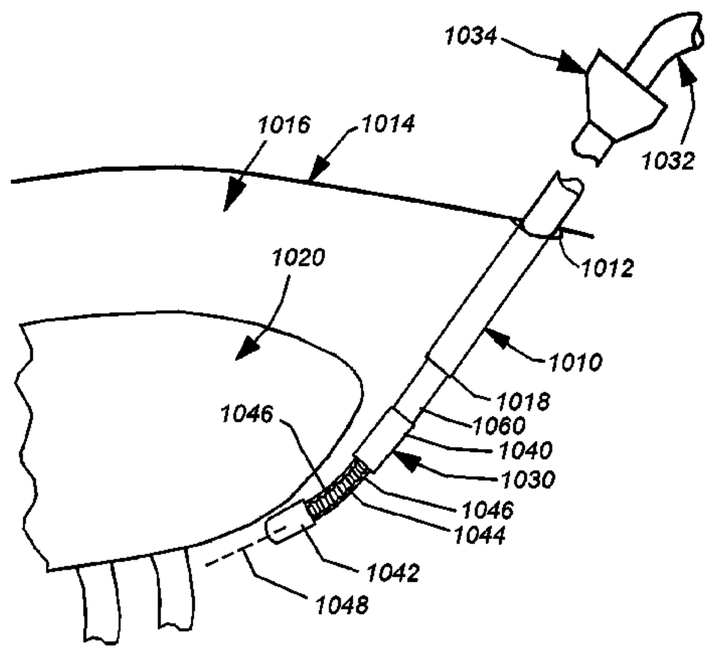
Assistant Examiner — Amanda Zink
(74) *Attorney, Agent, or Firm* — Adam M. Schoen; Brown Rudnick LLP

(57) **ABSTRACT**

This invention provides a system and method that allows a therapeutic device, such as an atrial fibrillation microwave ablation catheter or ablation tip to be guided to a remote location within a body cavity and then accurately immobilized on the tissue, including that of a moving organ, such as the heart.

10 Claims, 46 Drawing Sheets



Related U.S. Application Data

(60) Provisional application No. 60/744,016, filed on Mar. 31, 2006, provisional application No. 60/868,951, filed on Dec. 7, 2006.

(51) **Int. Cl.**

A61B 17/00	(2006.01)
A61B 18/00	(2006.01)
A61M 25/02	(2006.01)

(52) **U.S. Cl.**

CPC *A61M 25/0155* (2013.01); *A61M 25/0158* (2013.01); *A61M 2025/0213* (2013.01)

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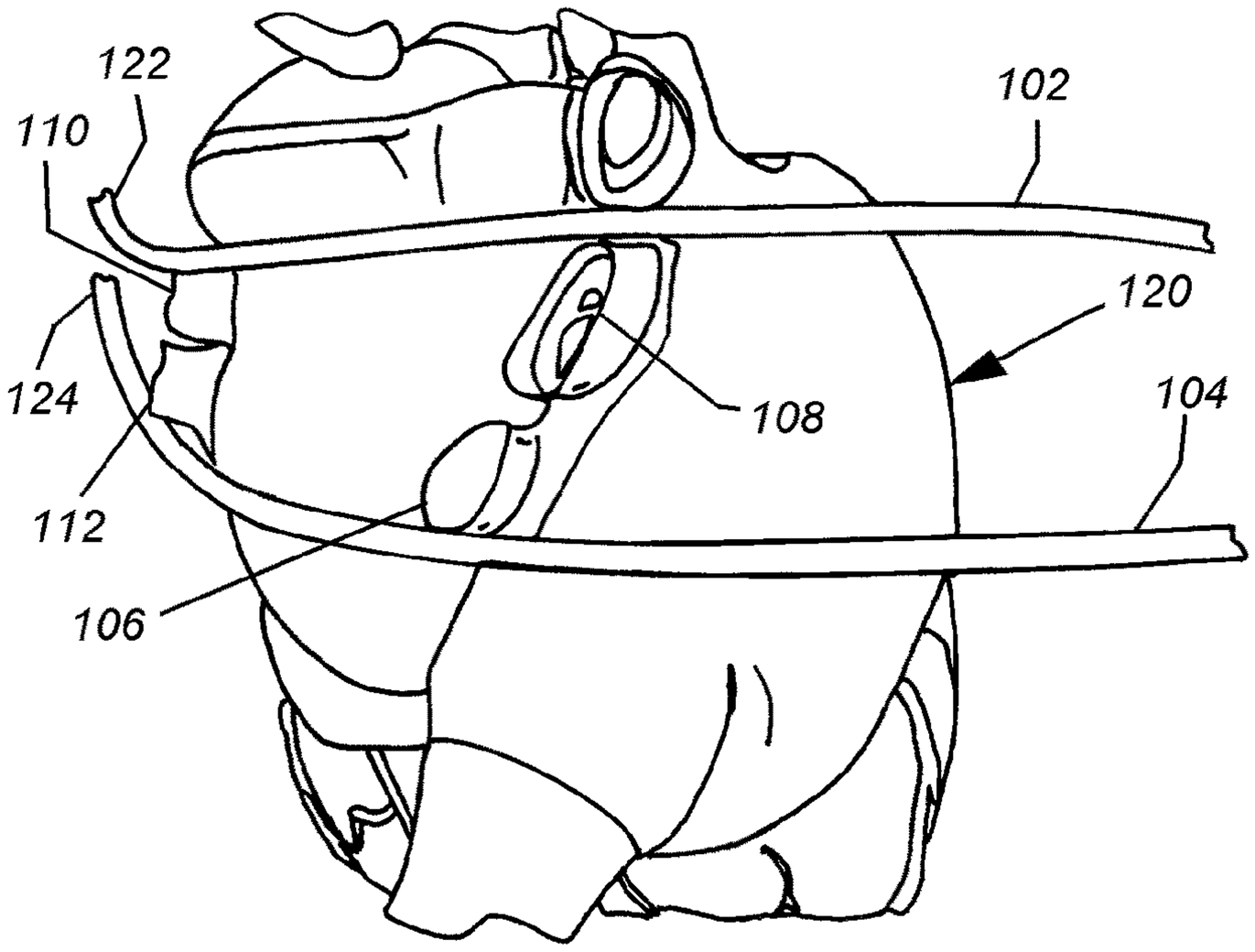


FIG. 1
(PRIOR ART)

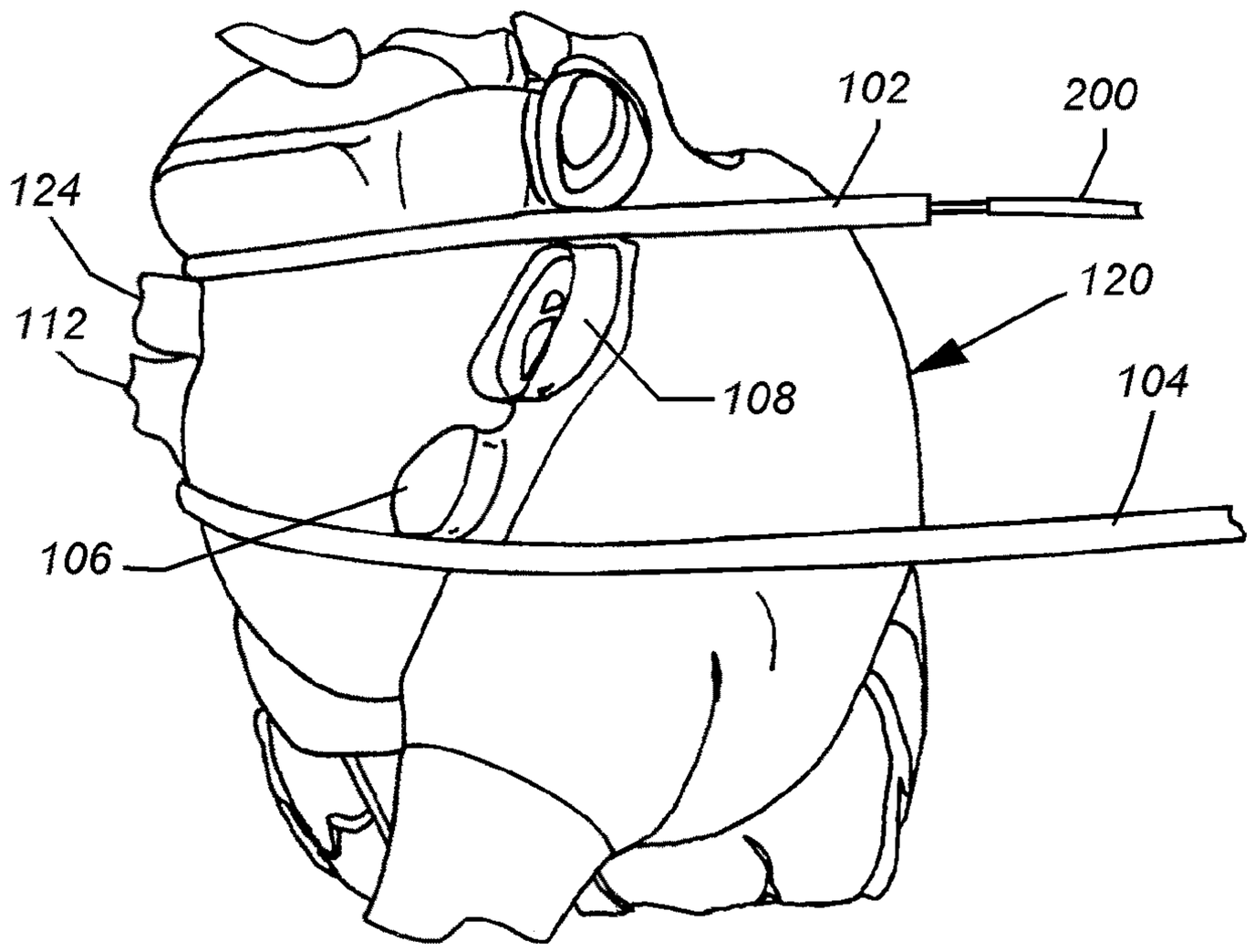


FIG. 2
(PRIOR ART)

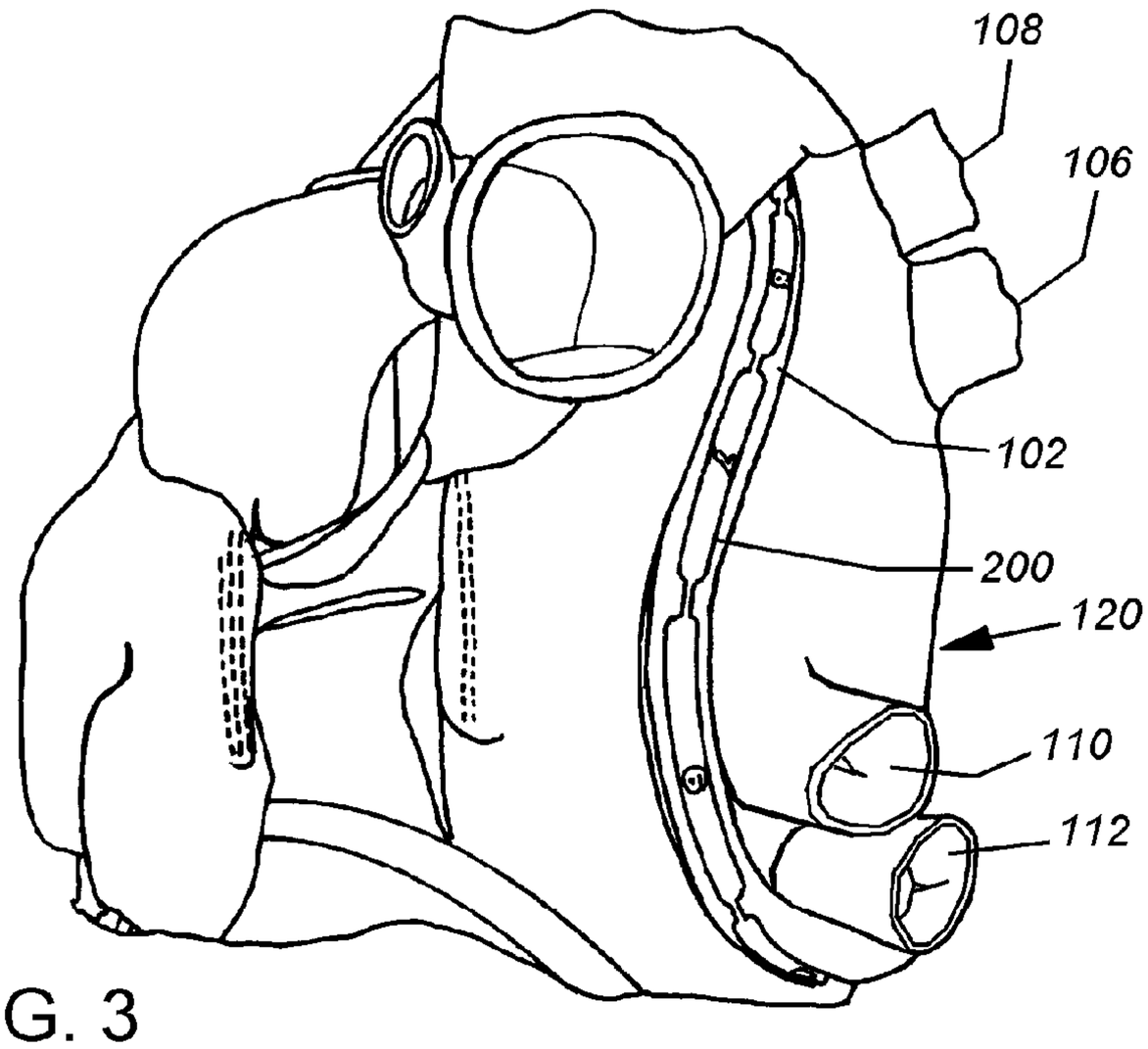


FIG. 3
(PRIOR ART)

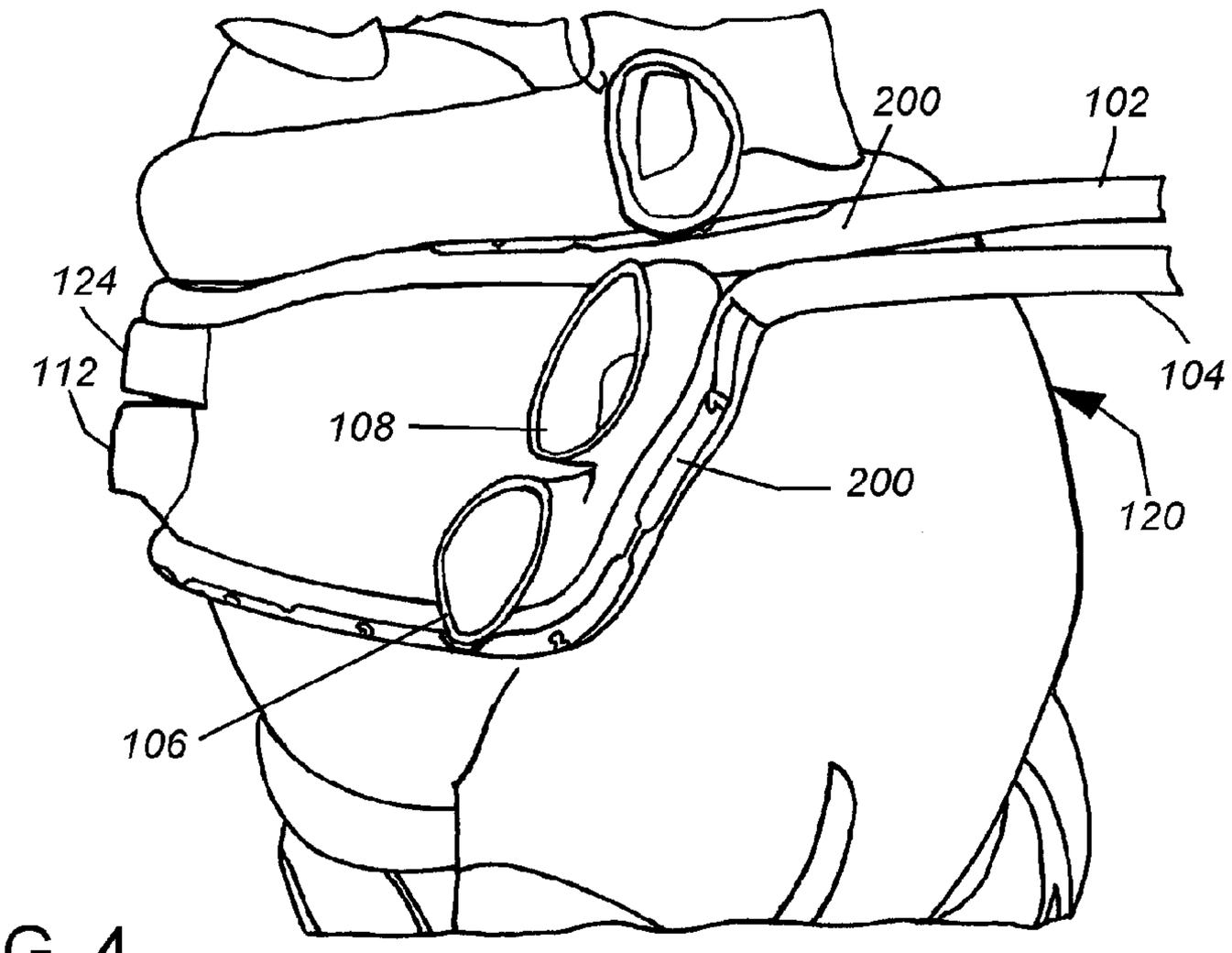


FIG. 4
(PRIOR ART)

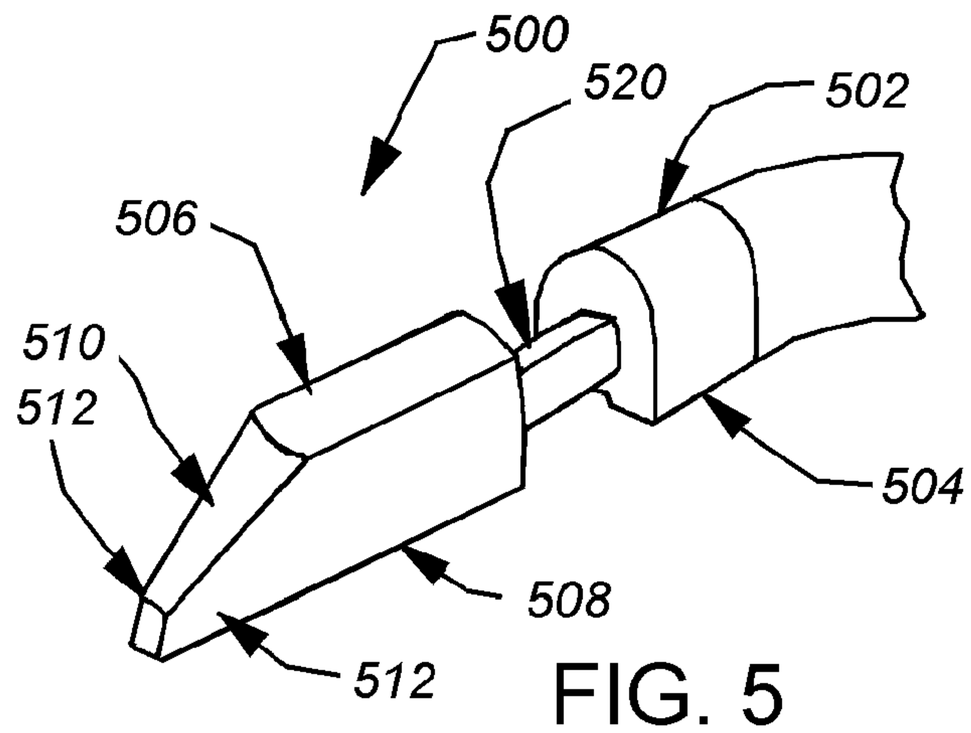
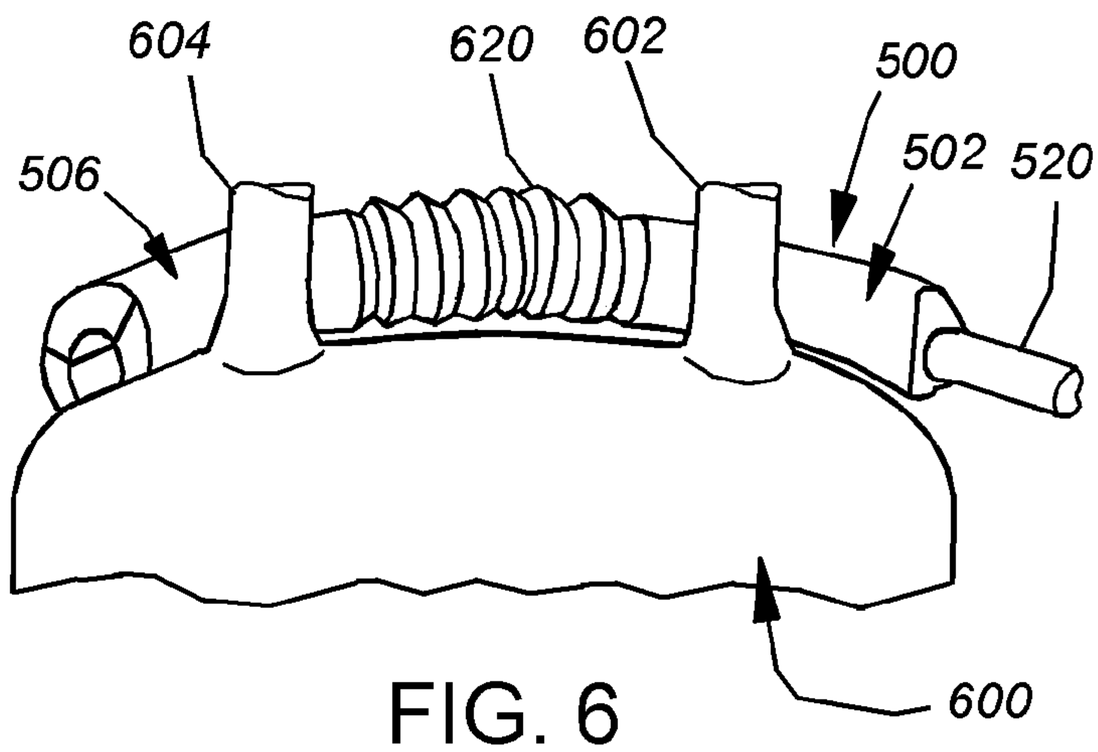


FIG. 5



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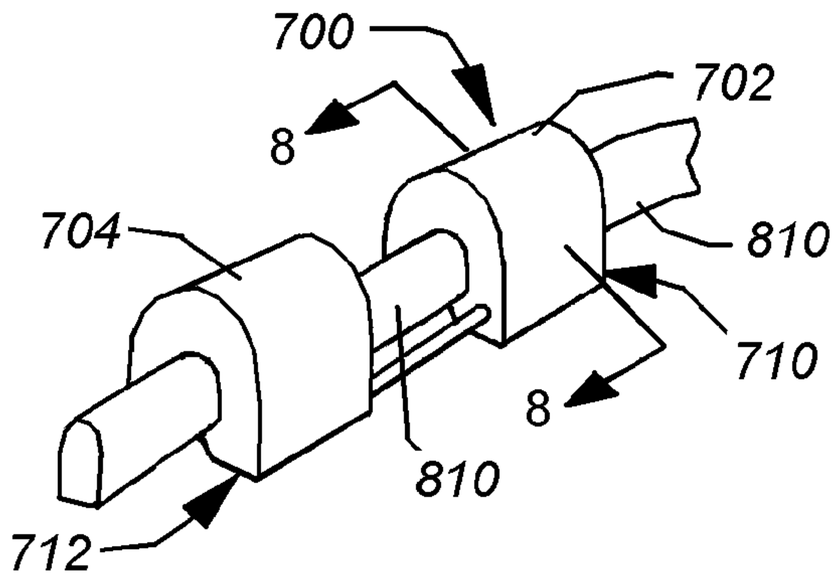

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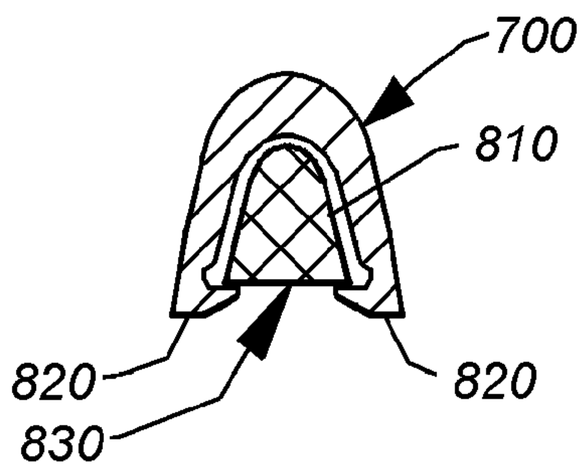

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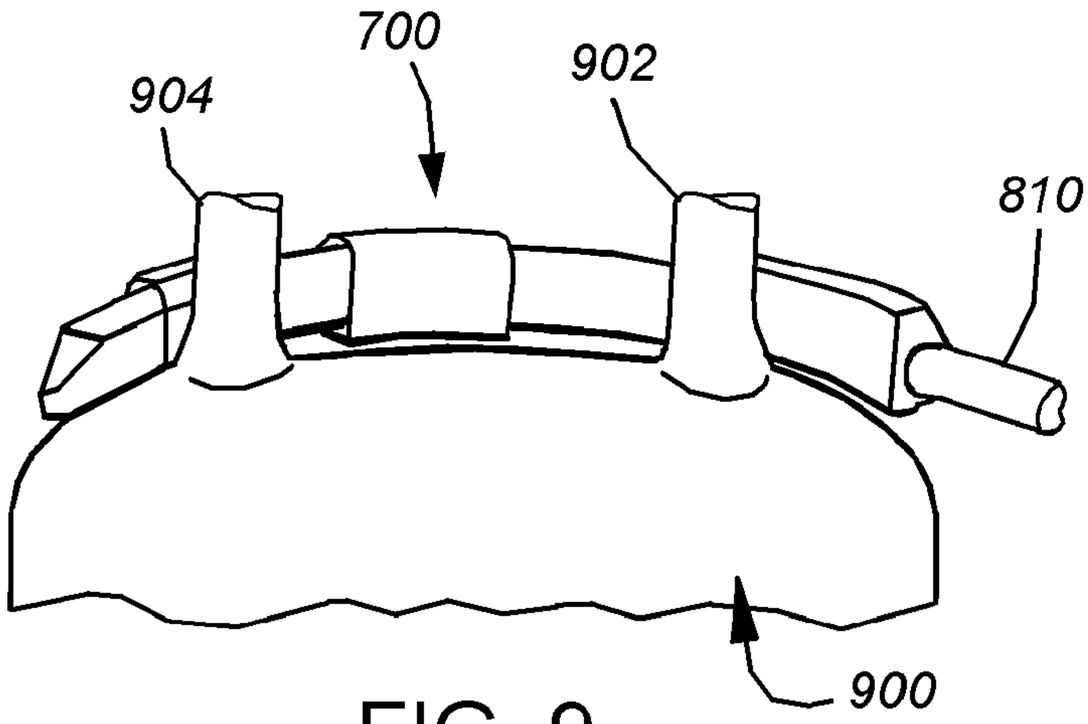
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FIG. 9

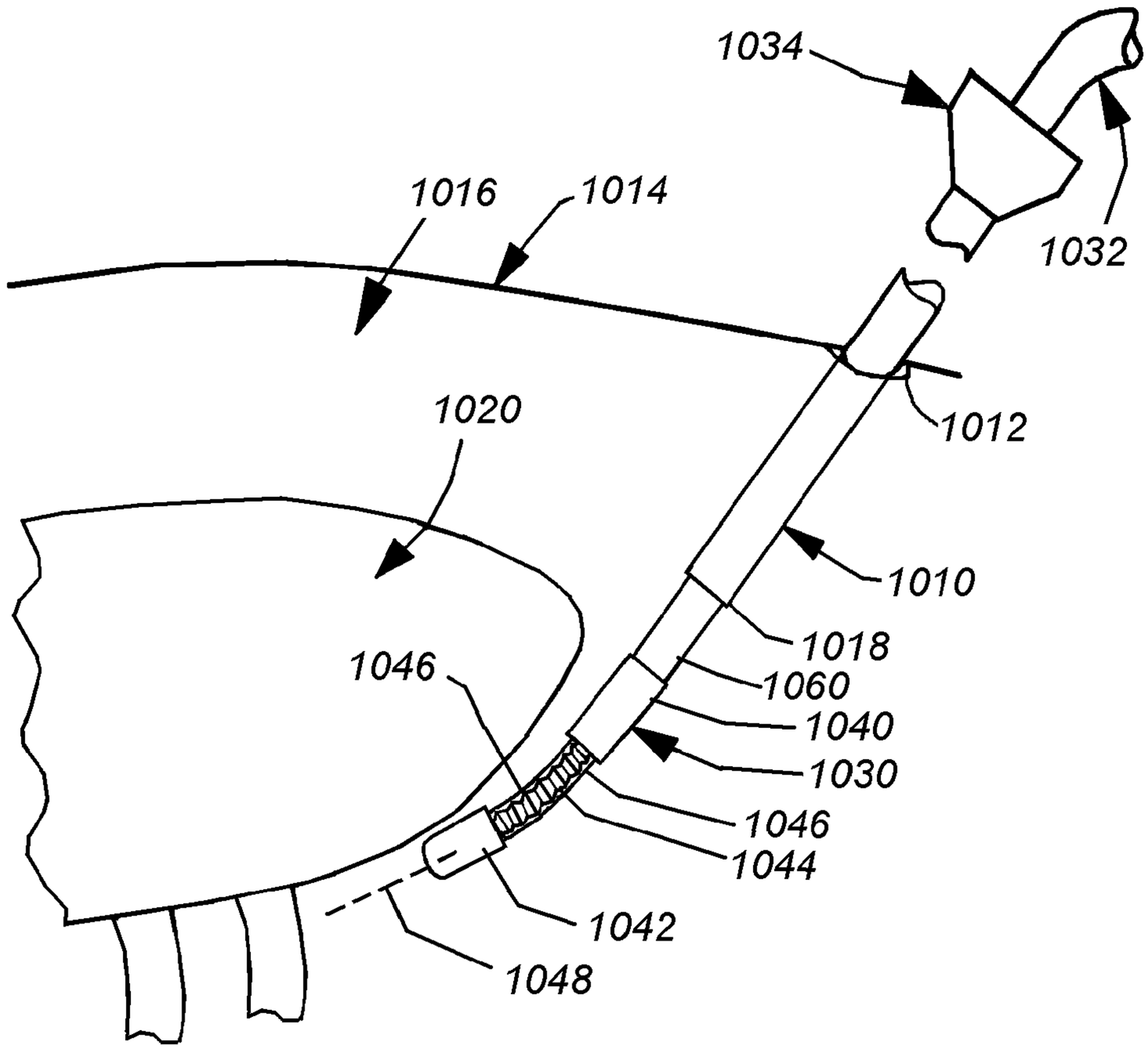
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FIG. 10

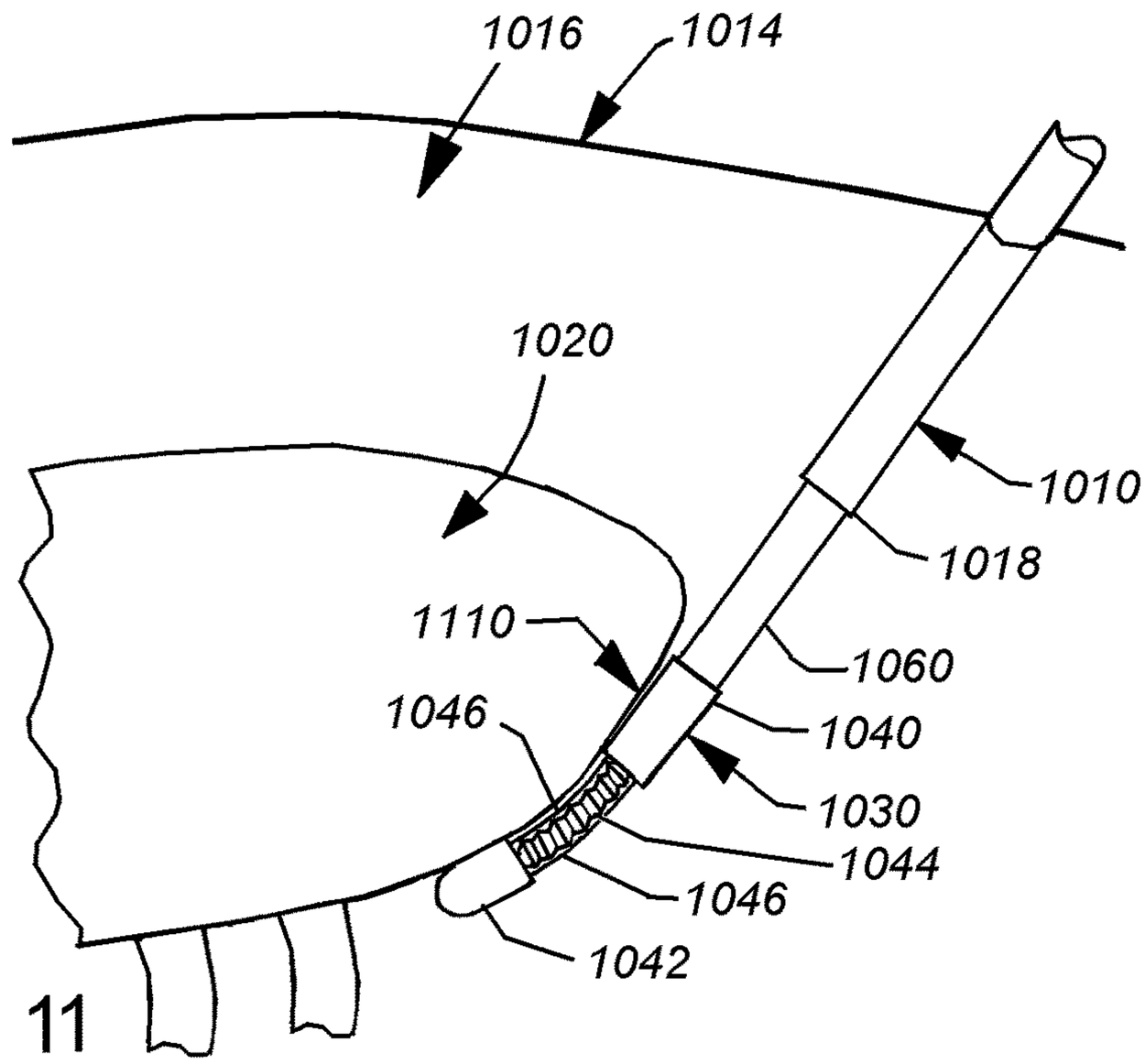
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FIG. 11

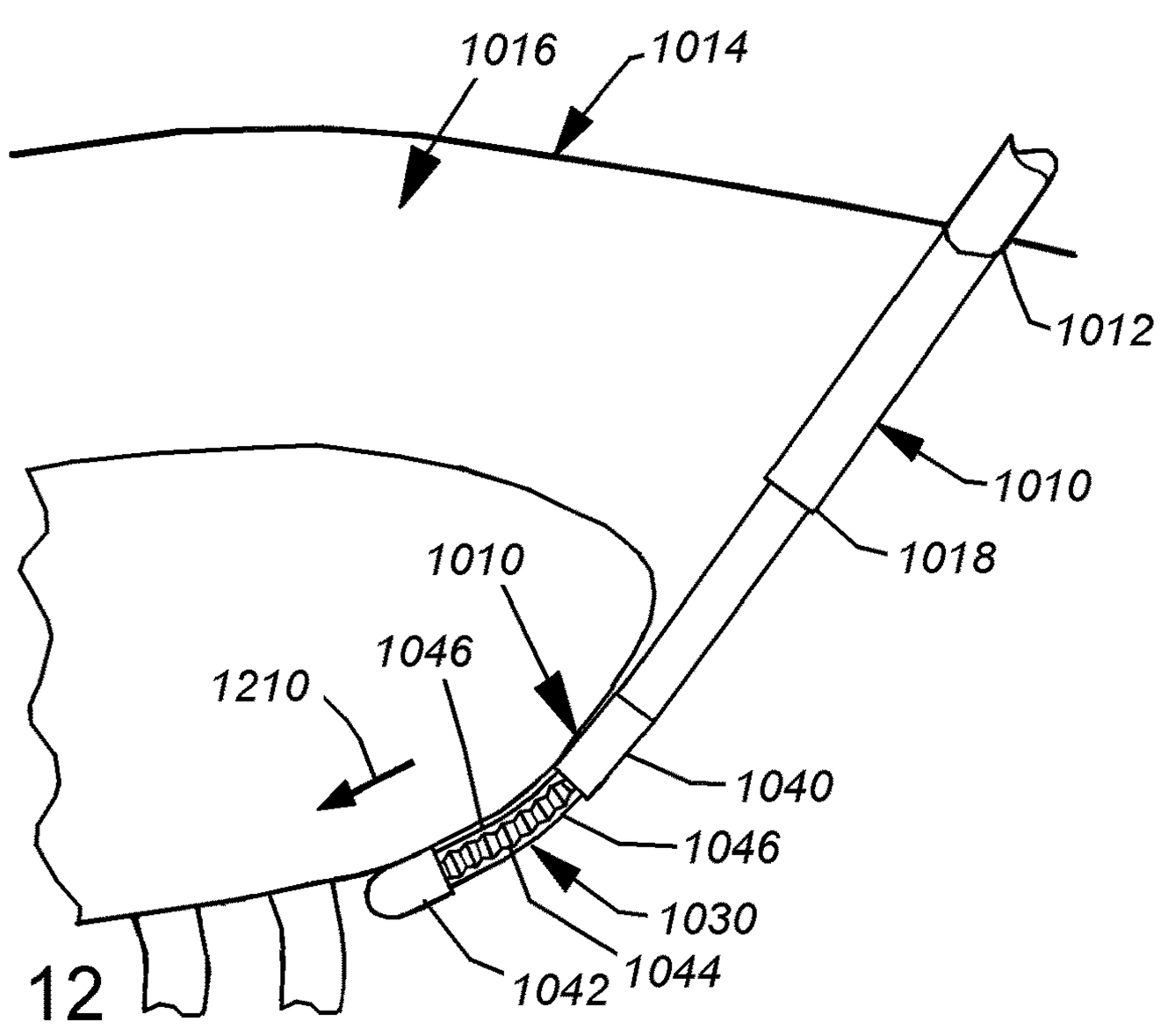
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FIG. 12

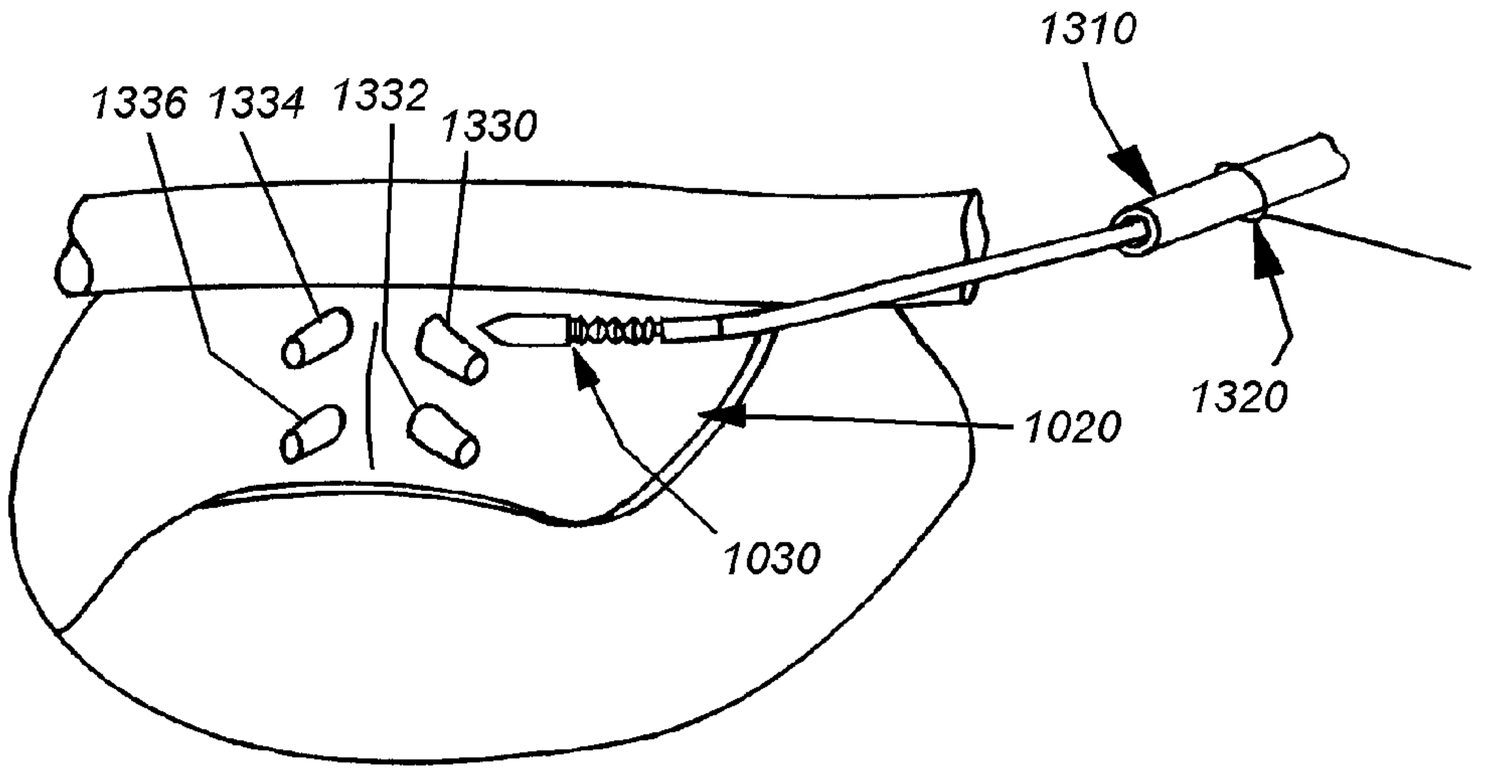
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FIG. 13

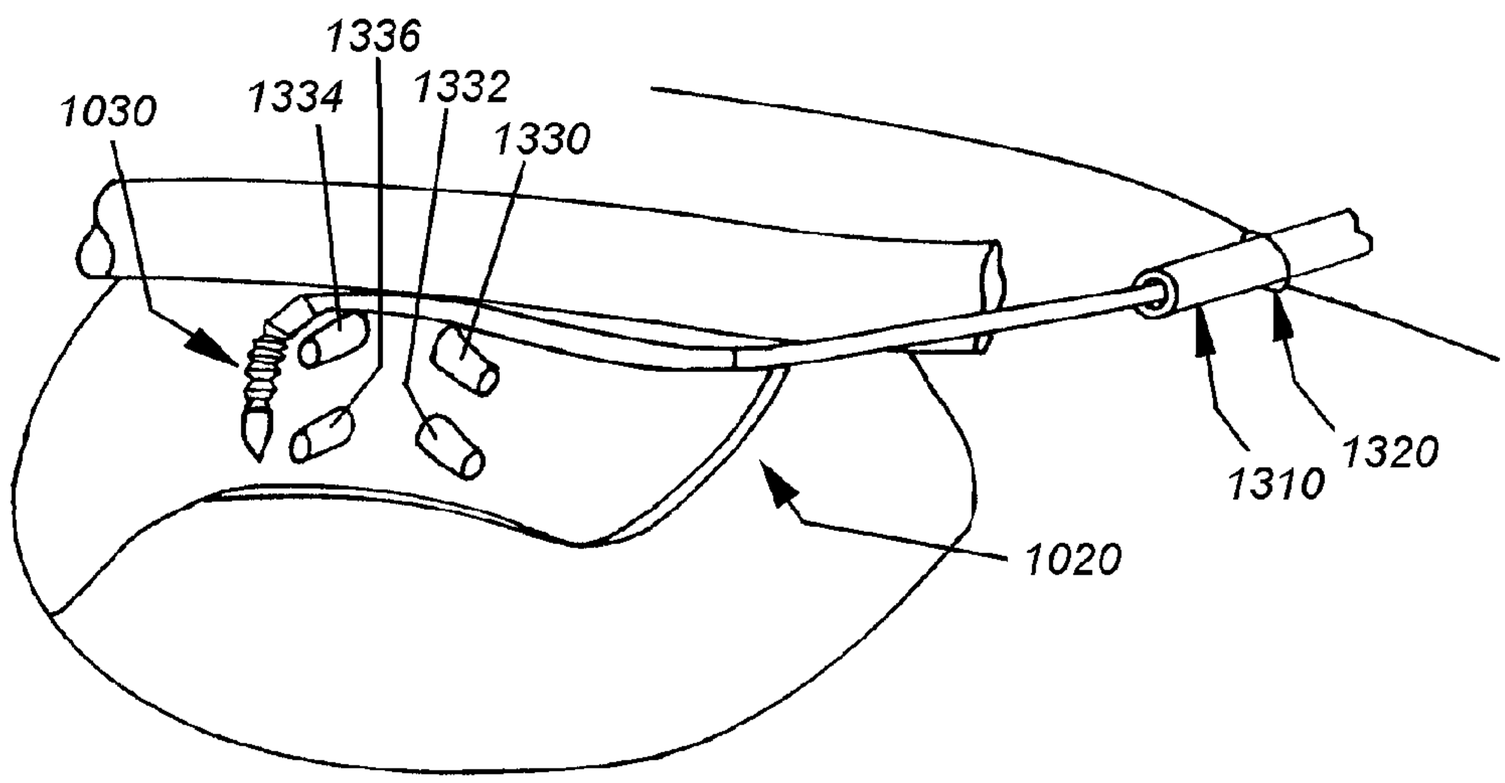
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FIG. 14

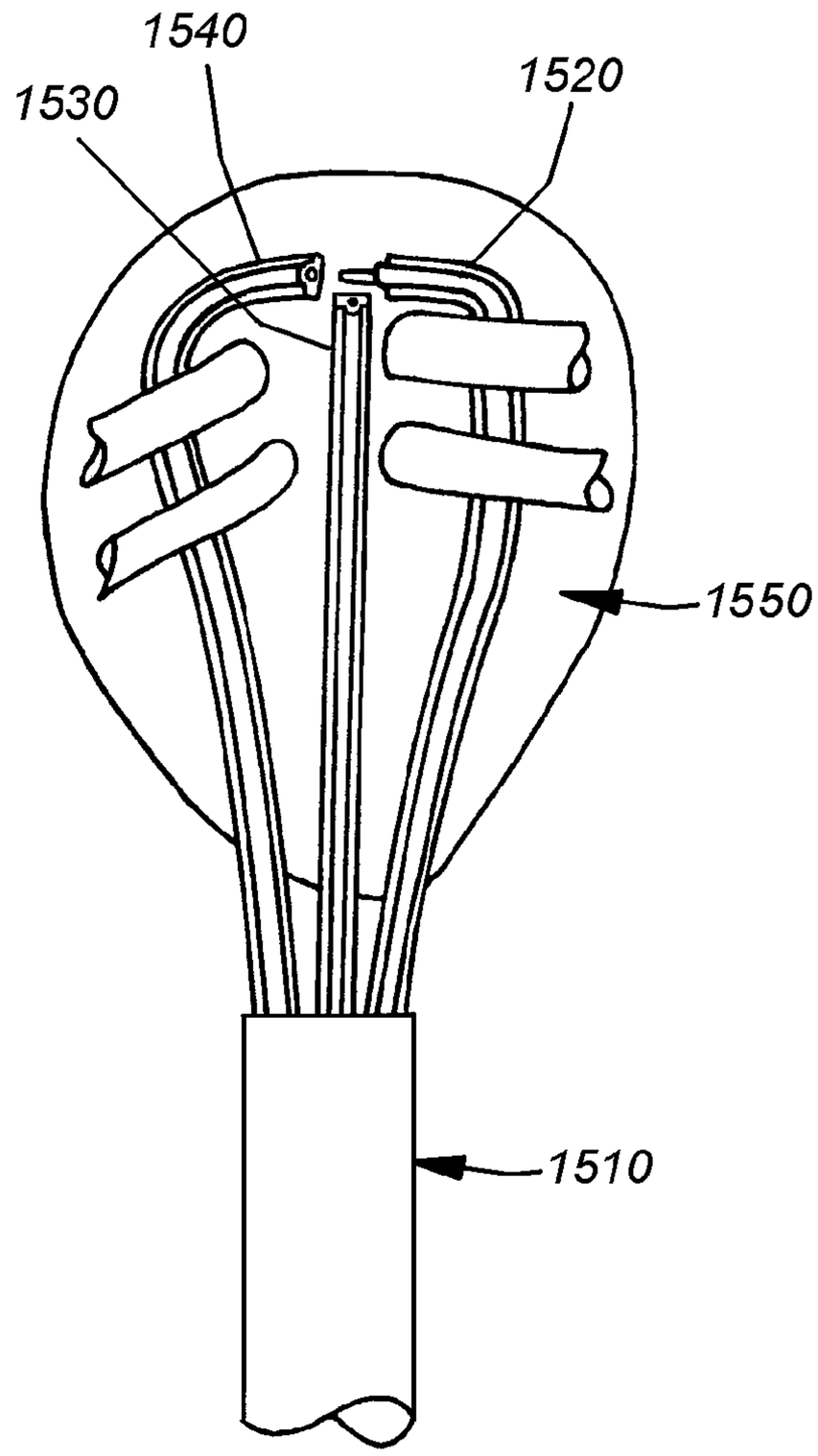

FIG. 15

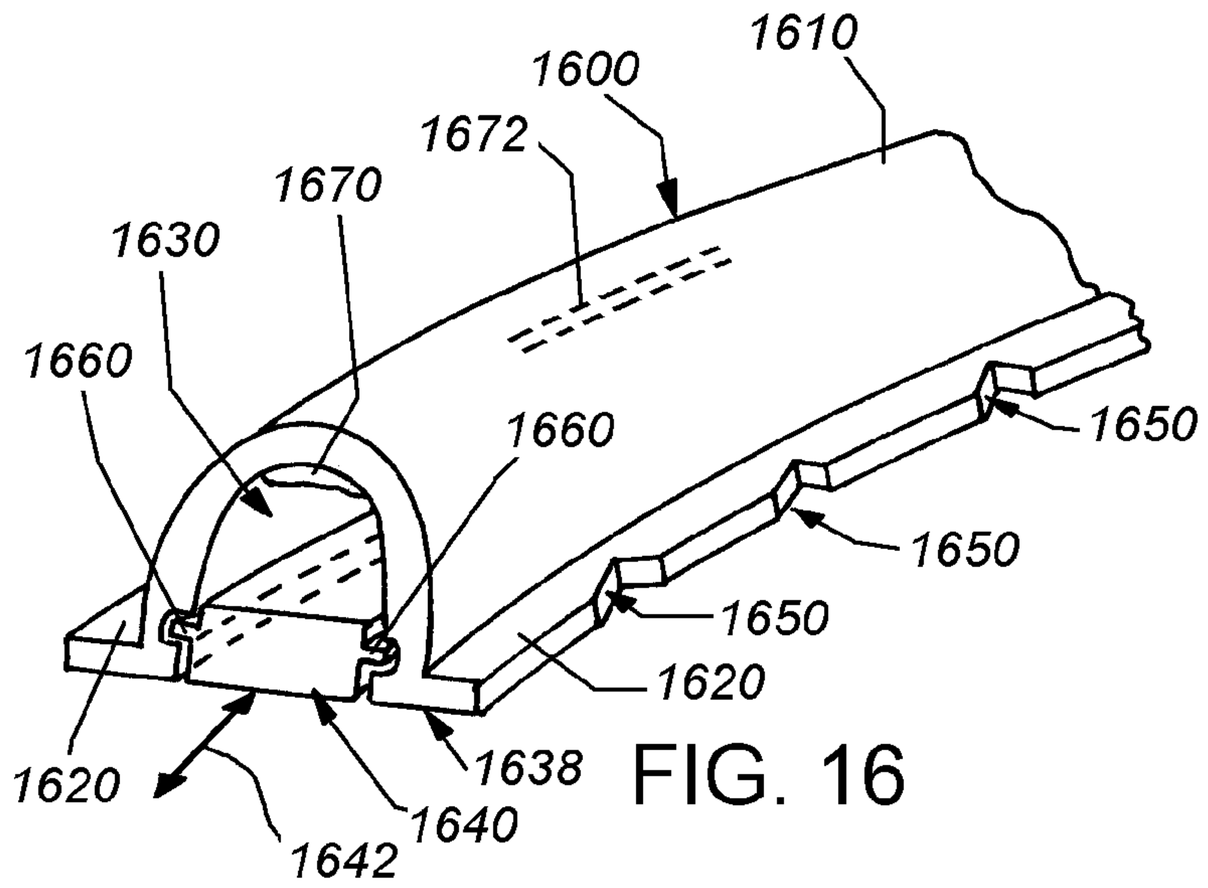
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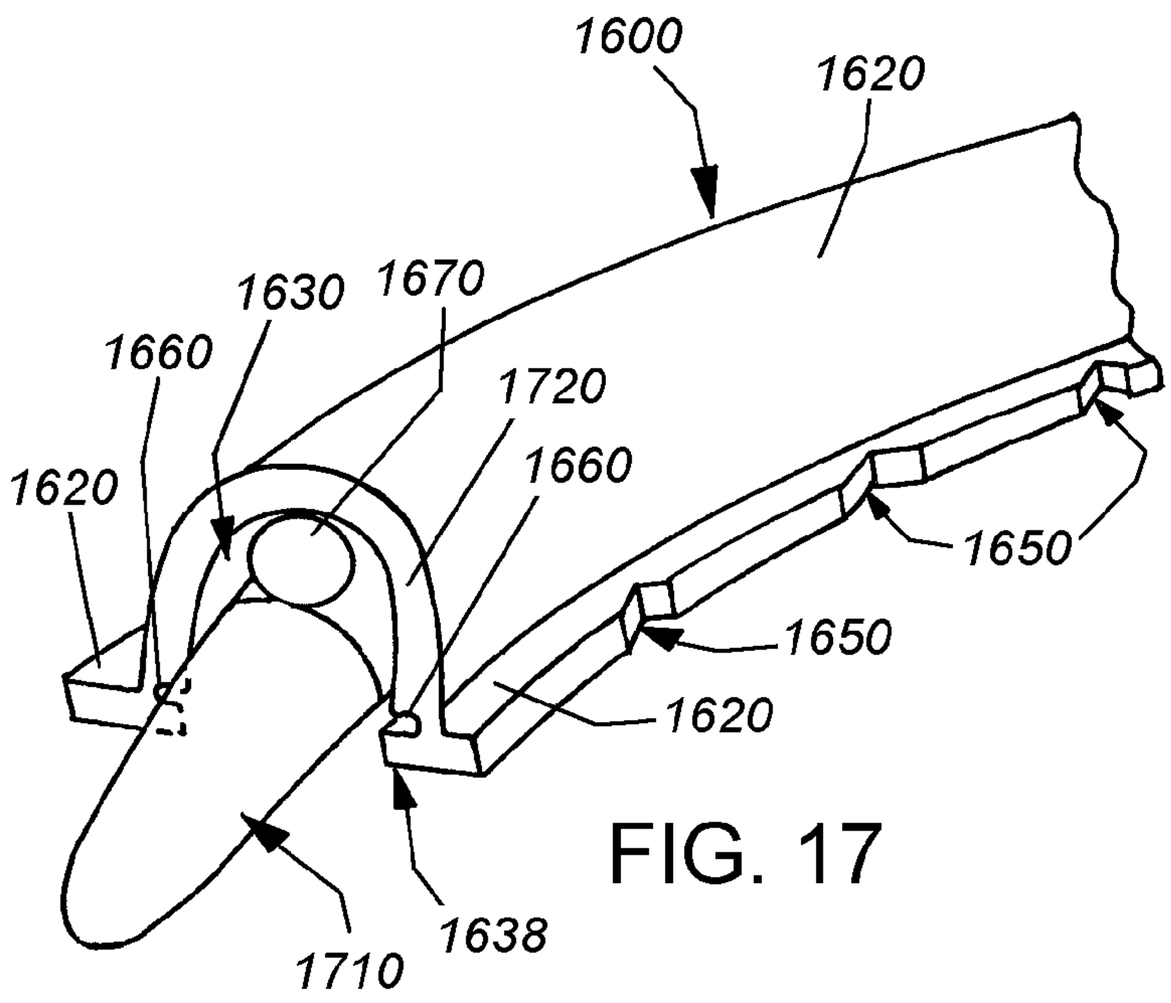
FIG. 16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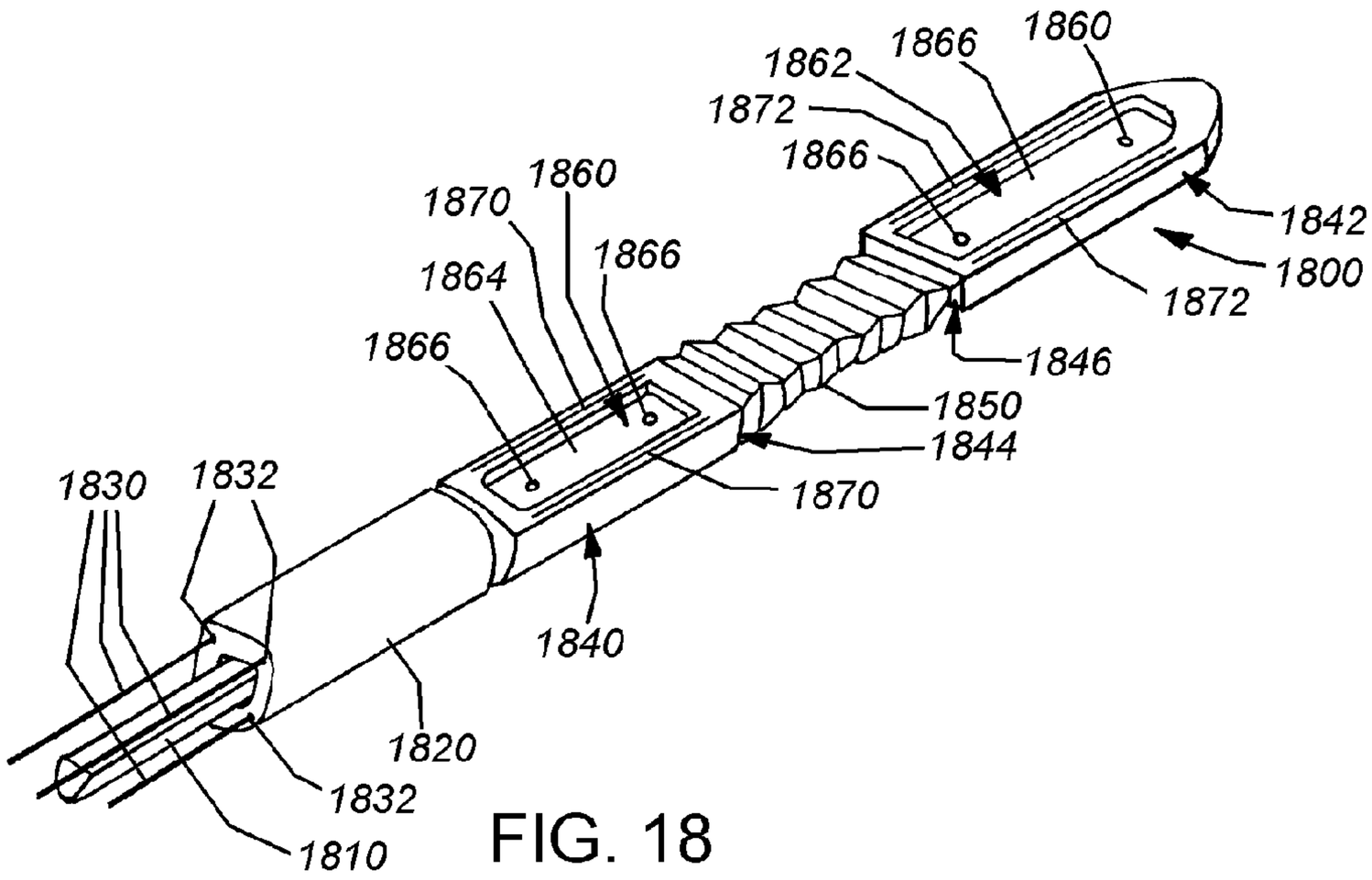
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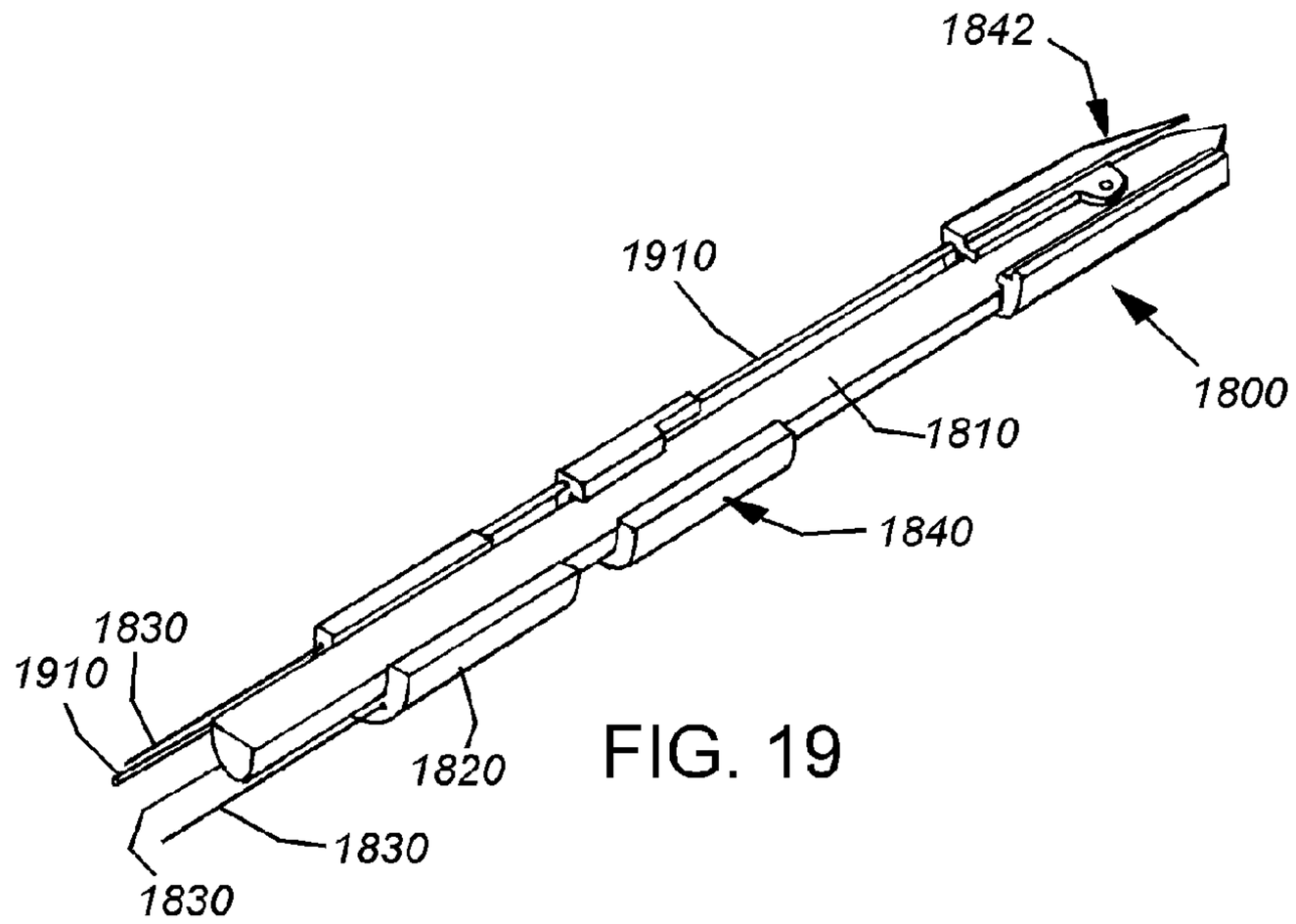
FIG. 18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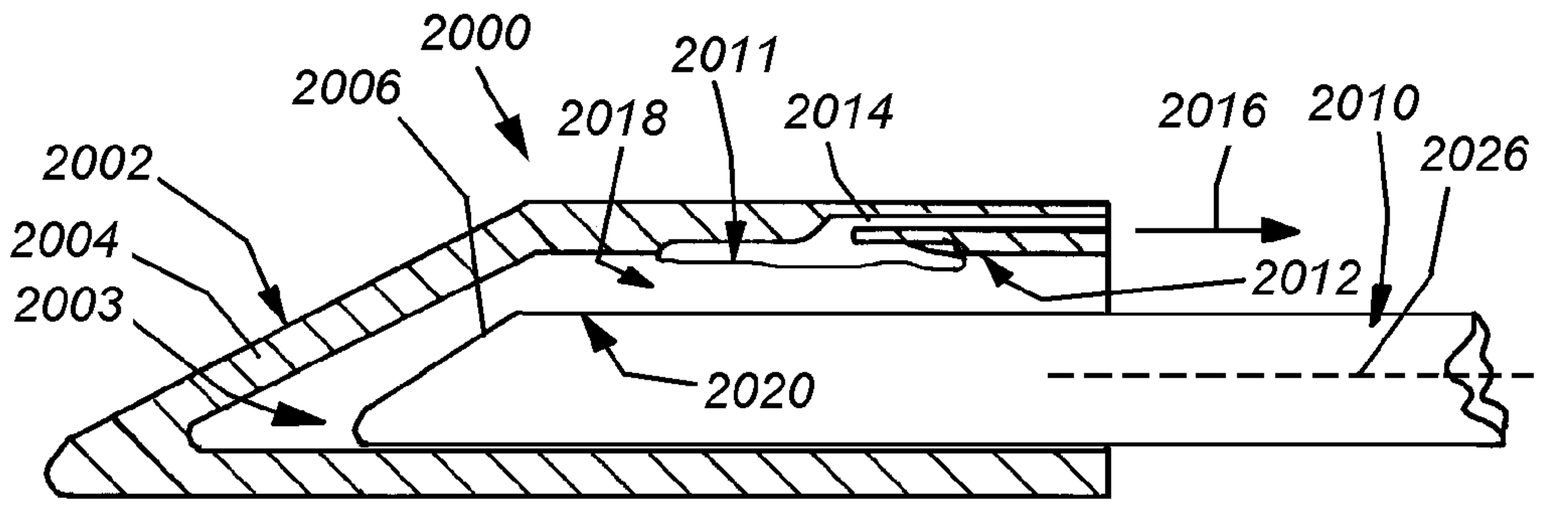


FIG. 20A

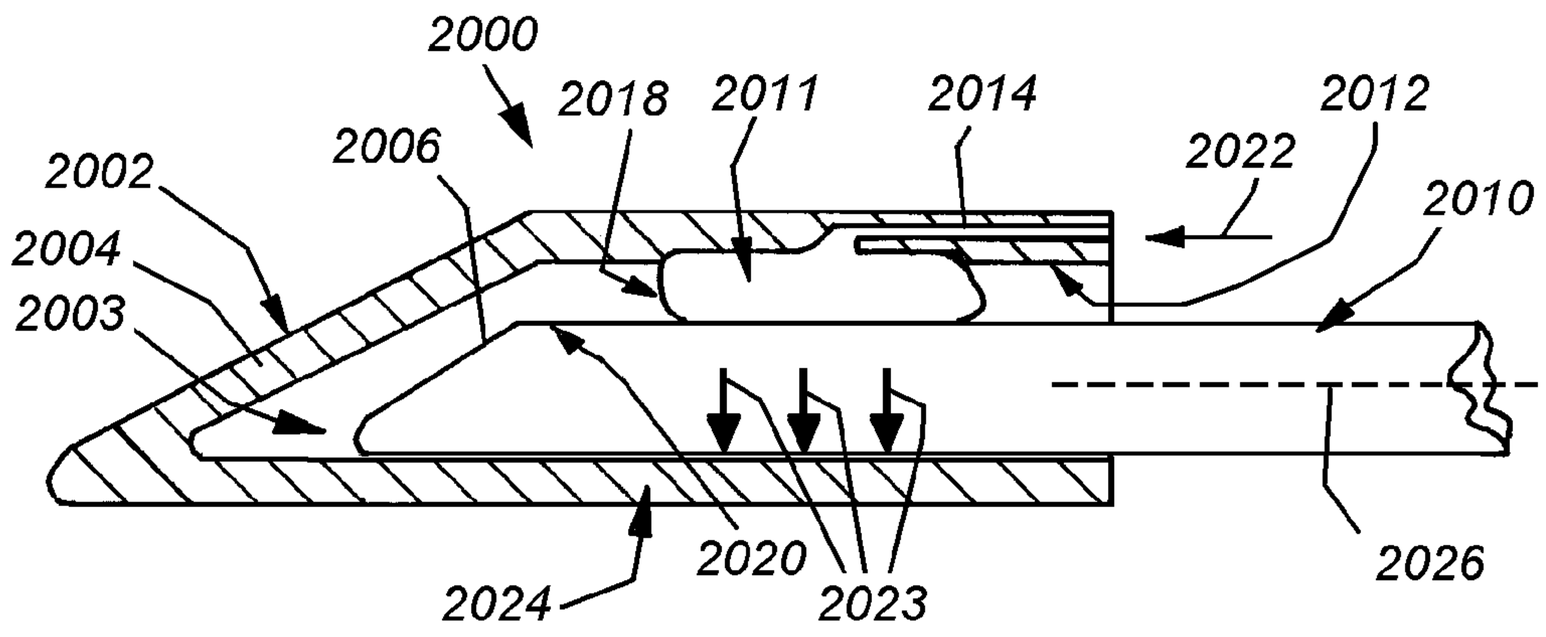


FIG. 20B

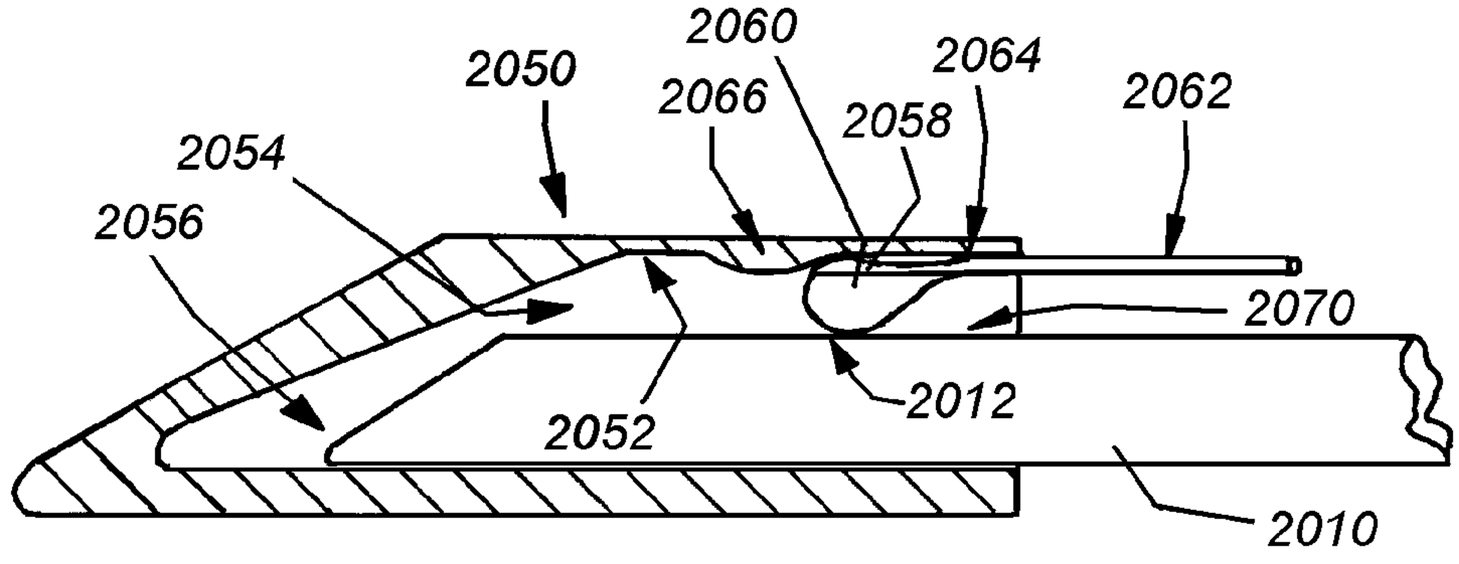


FIG. 20C

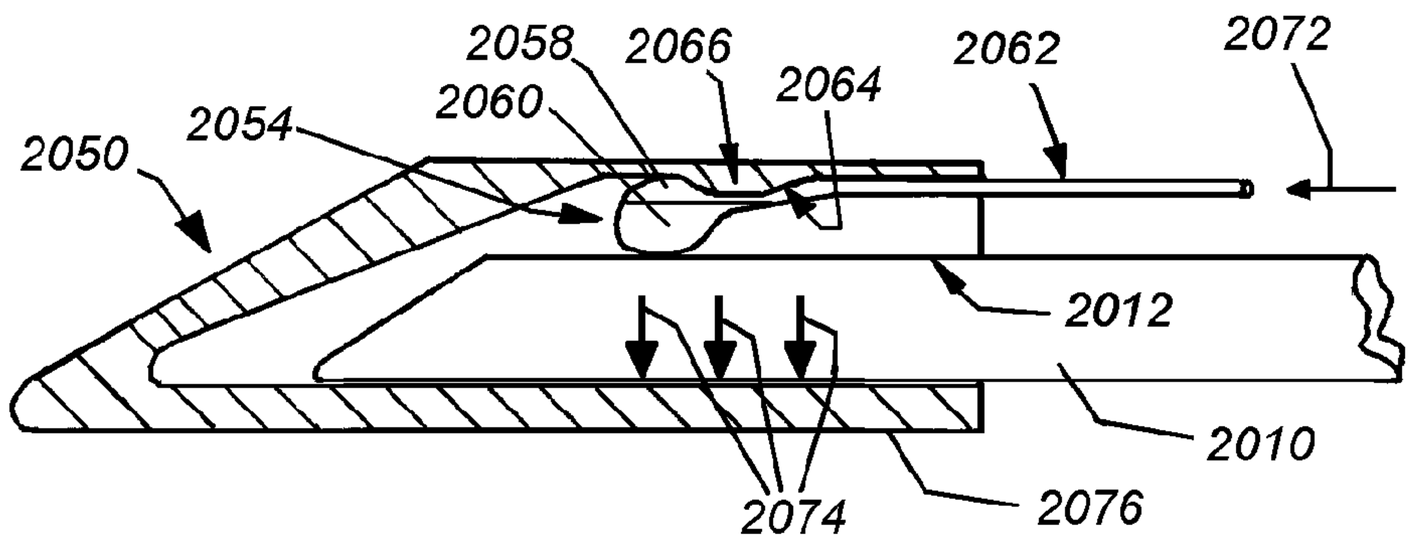


FIG. 20D

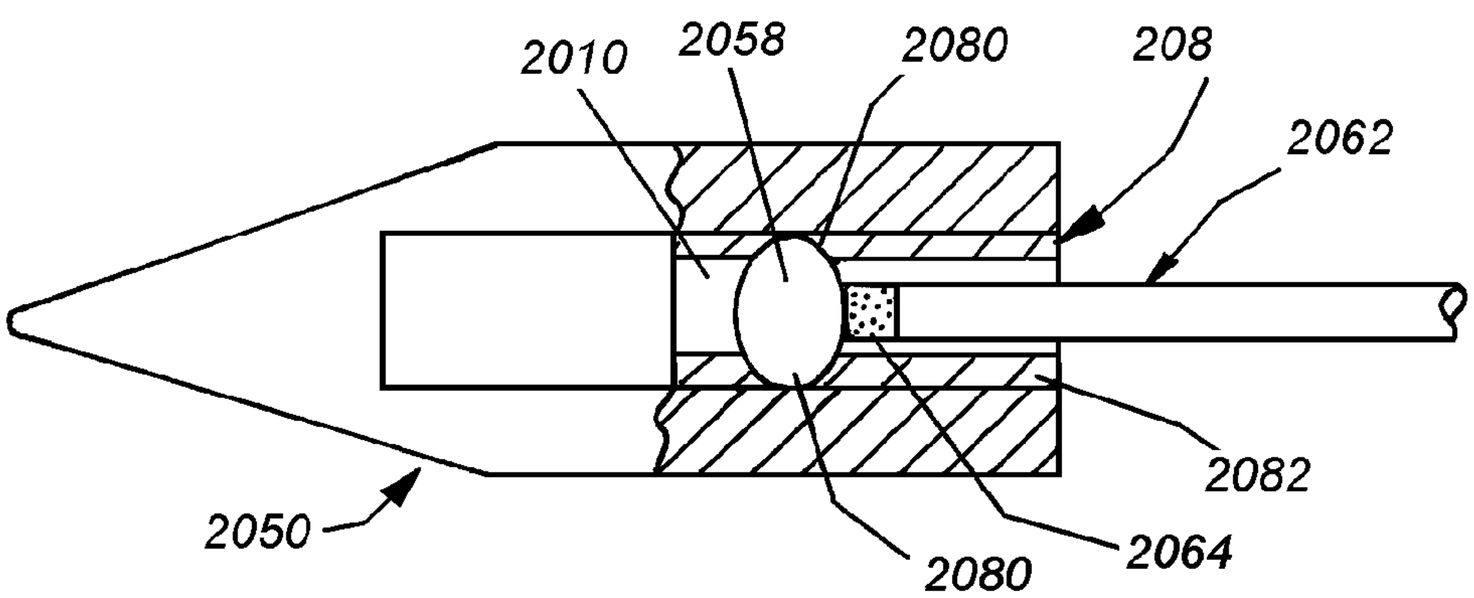
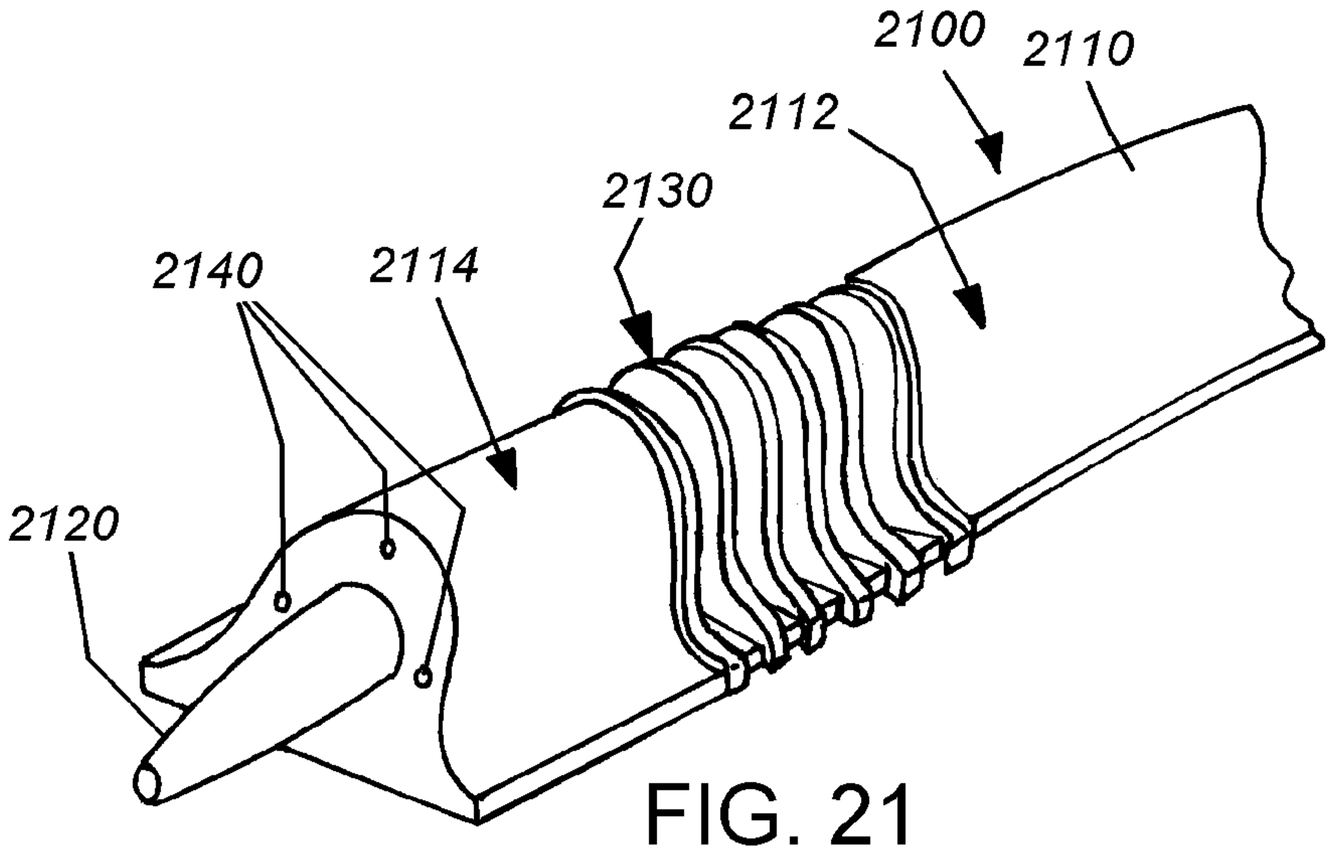


FIG. 20E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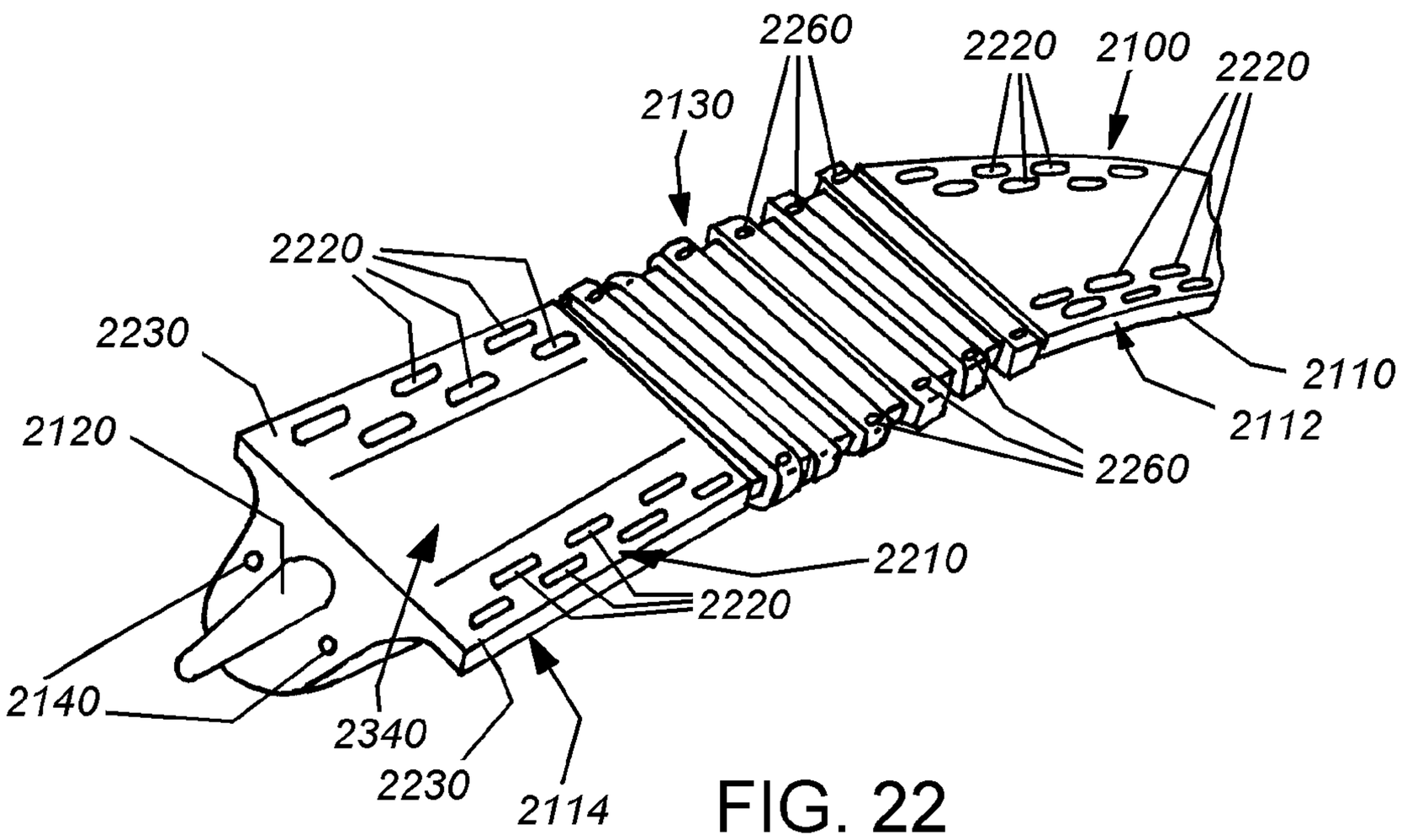
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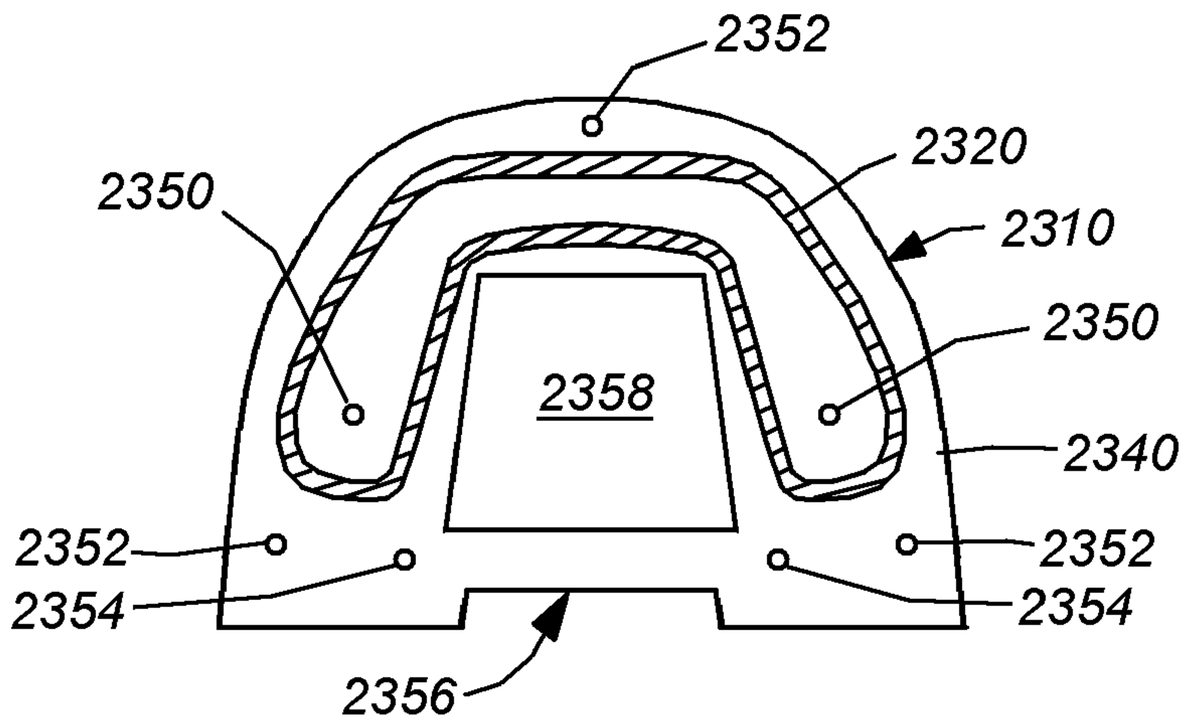
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FIG. 23

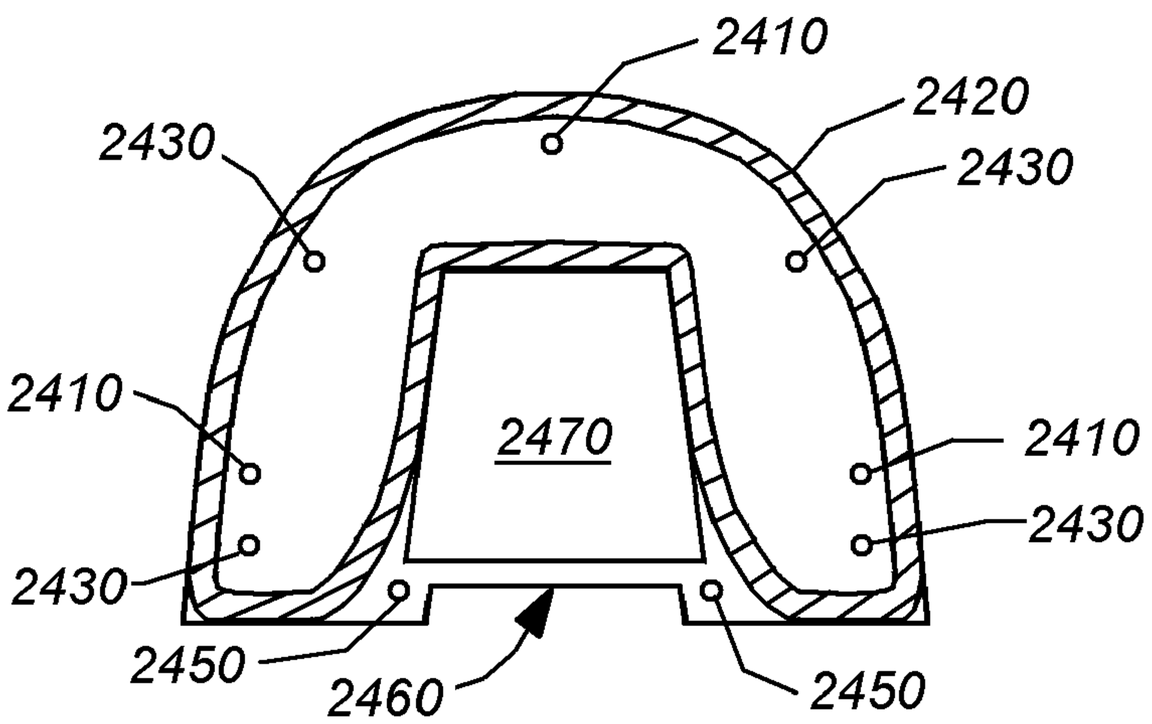
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FIG. 24

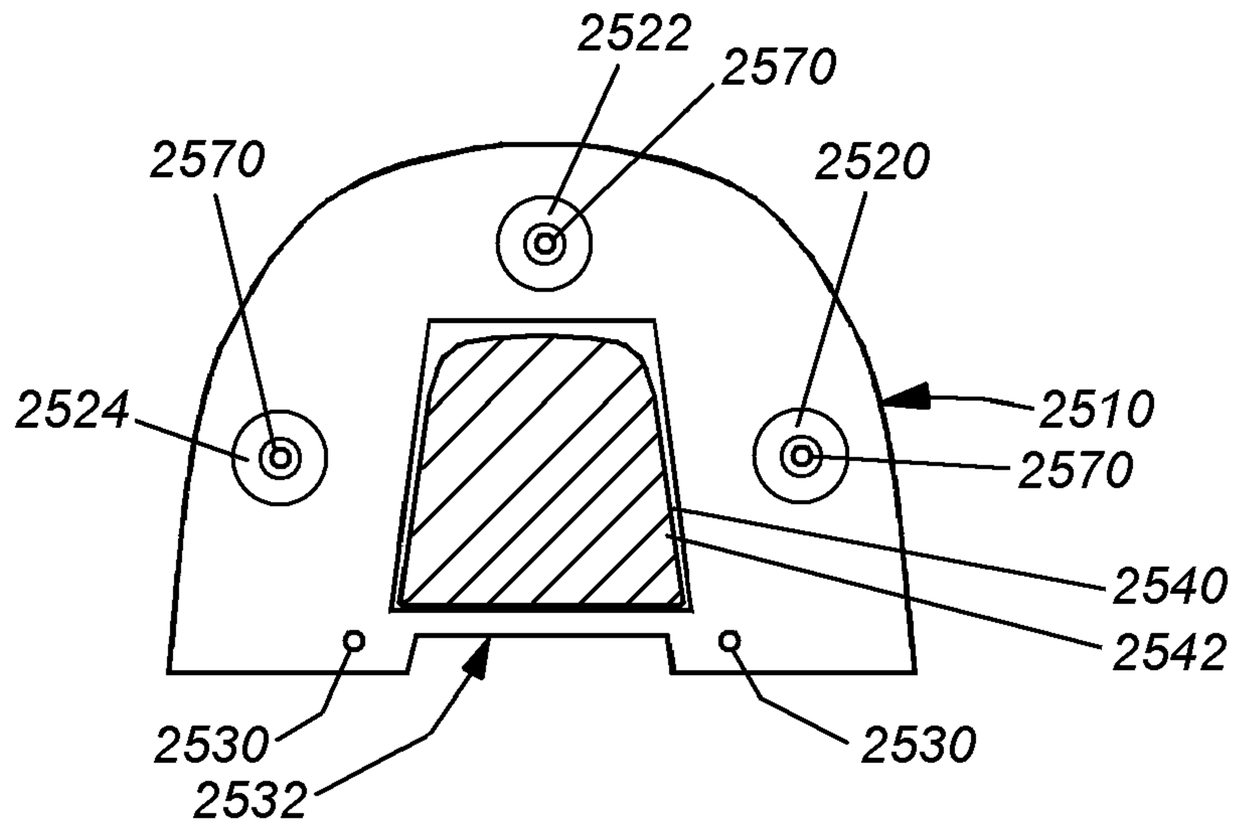
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FIG. 25

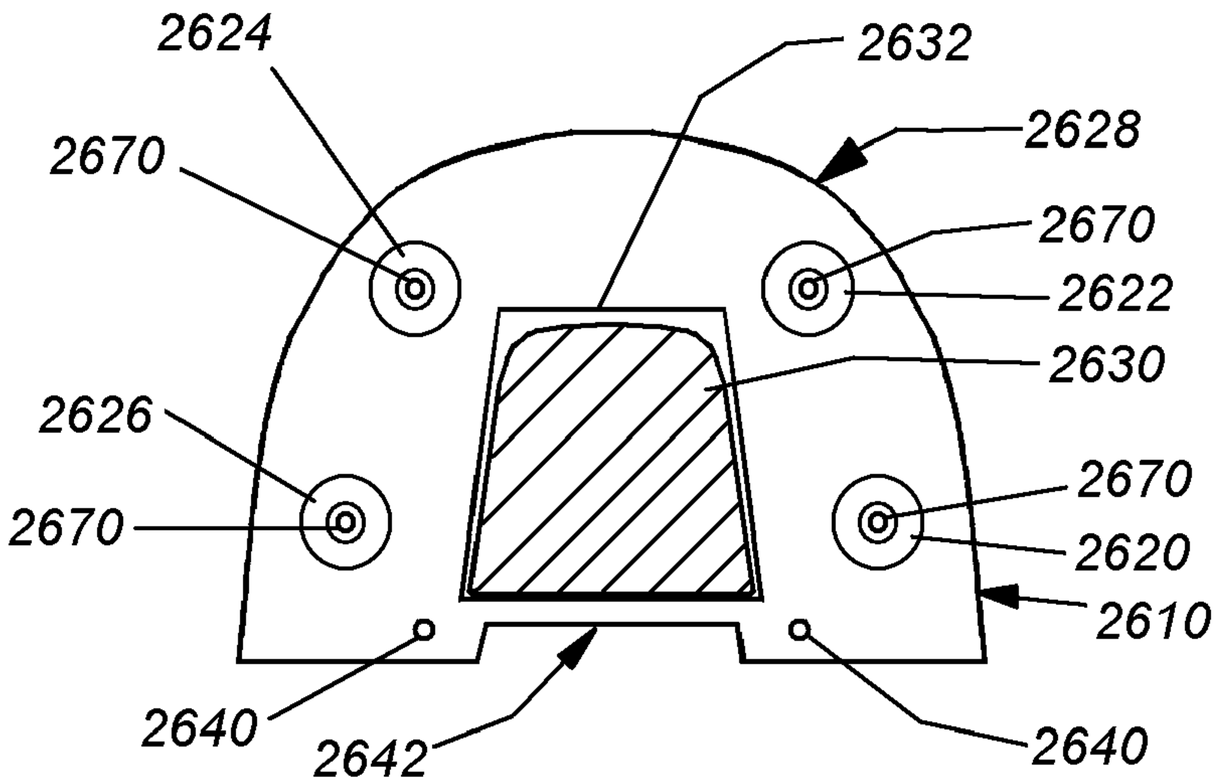
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FIG. 26

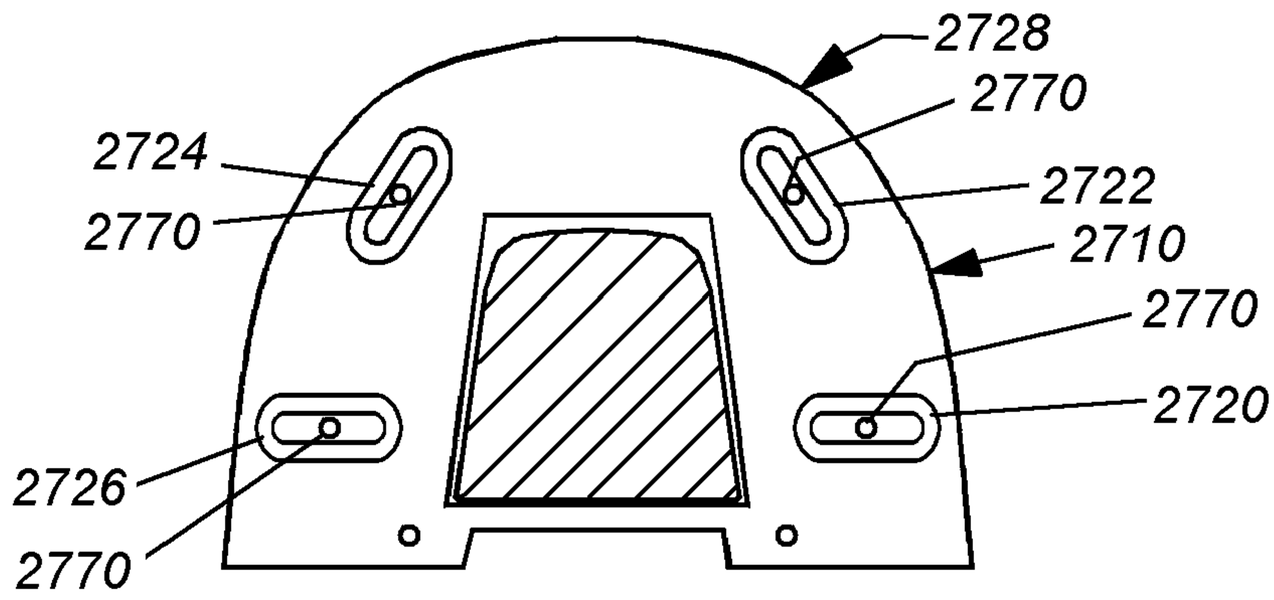
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FIG. 27

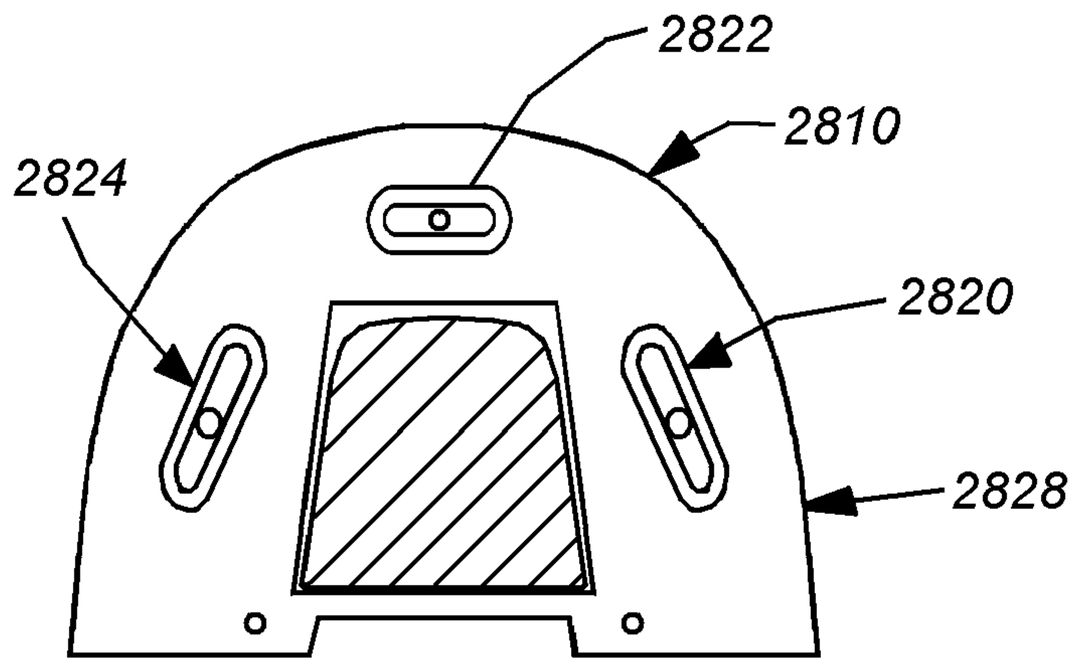
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FIG. 28

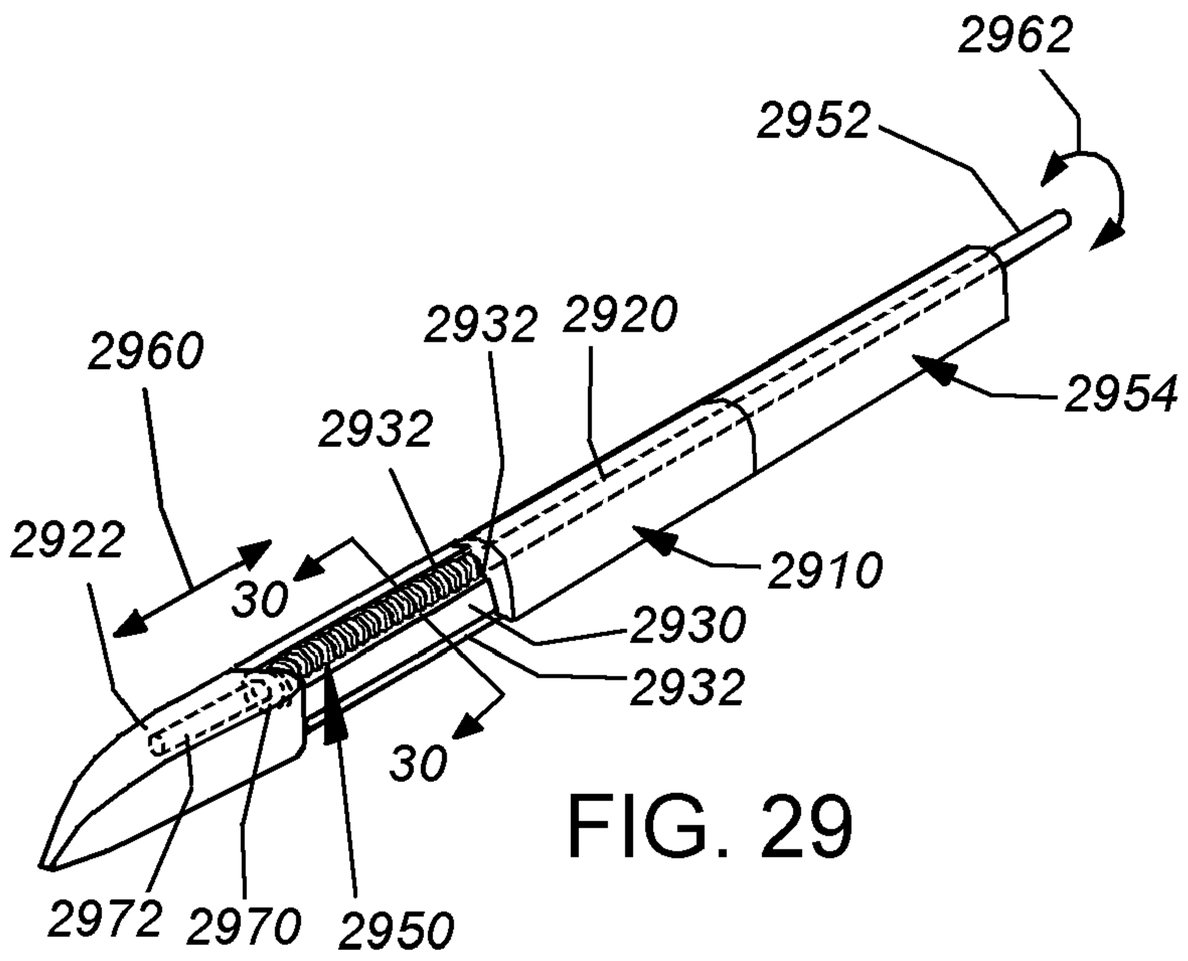
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FIG. 29

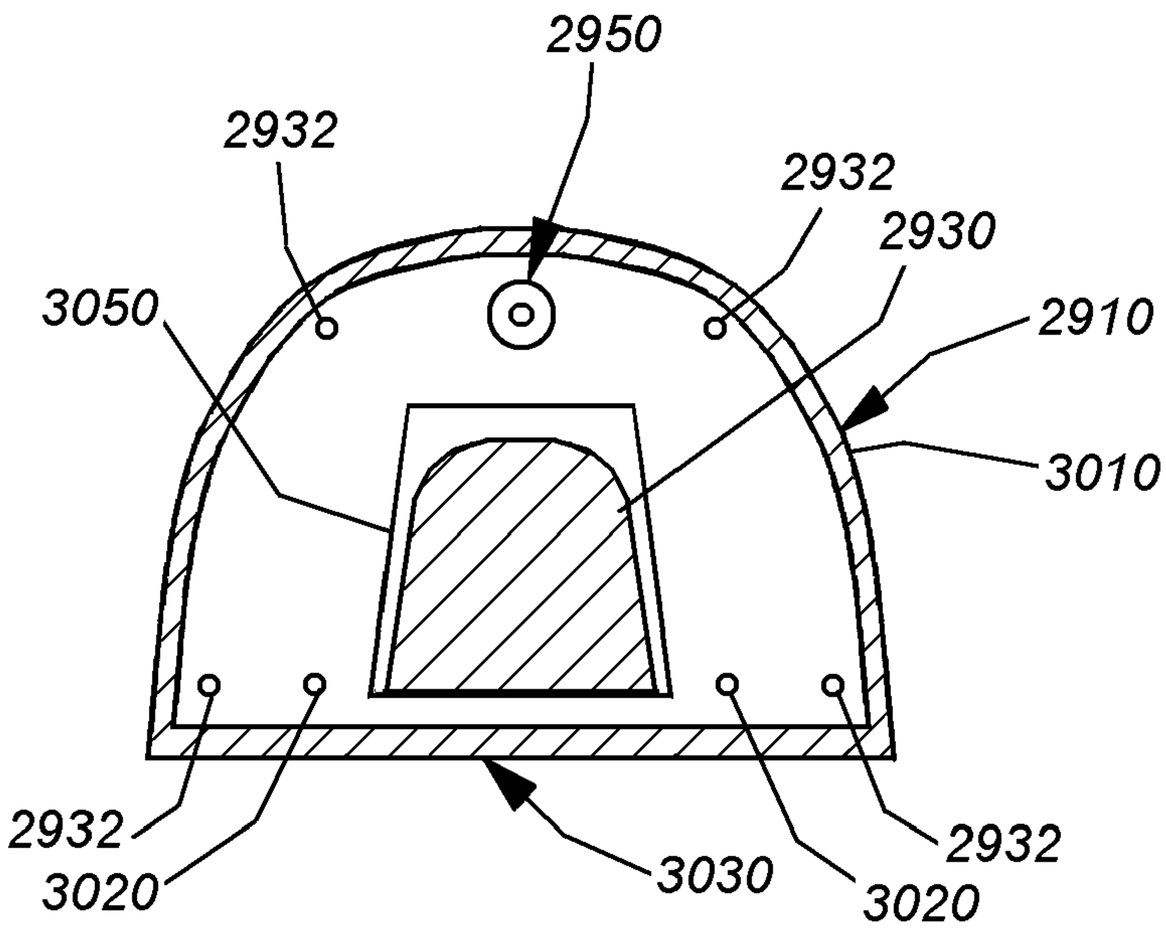
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FIG. 30

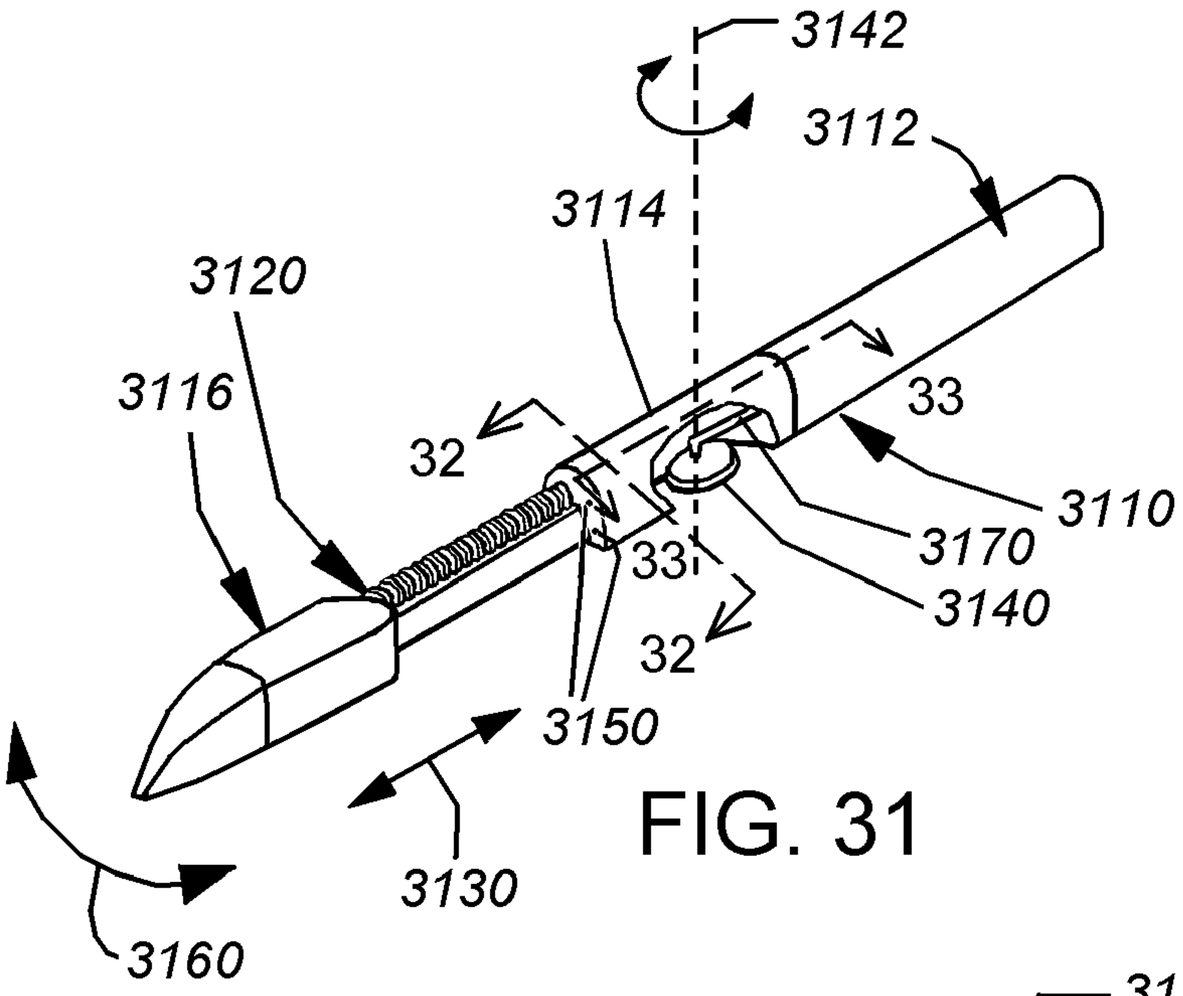

FIG. 31

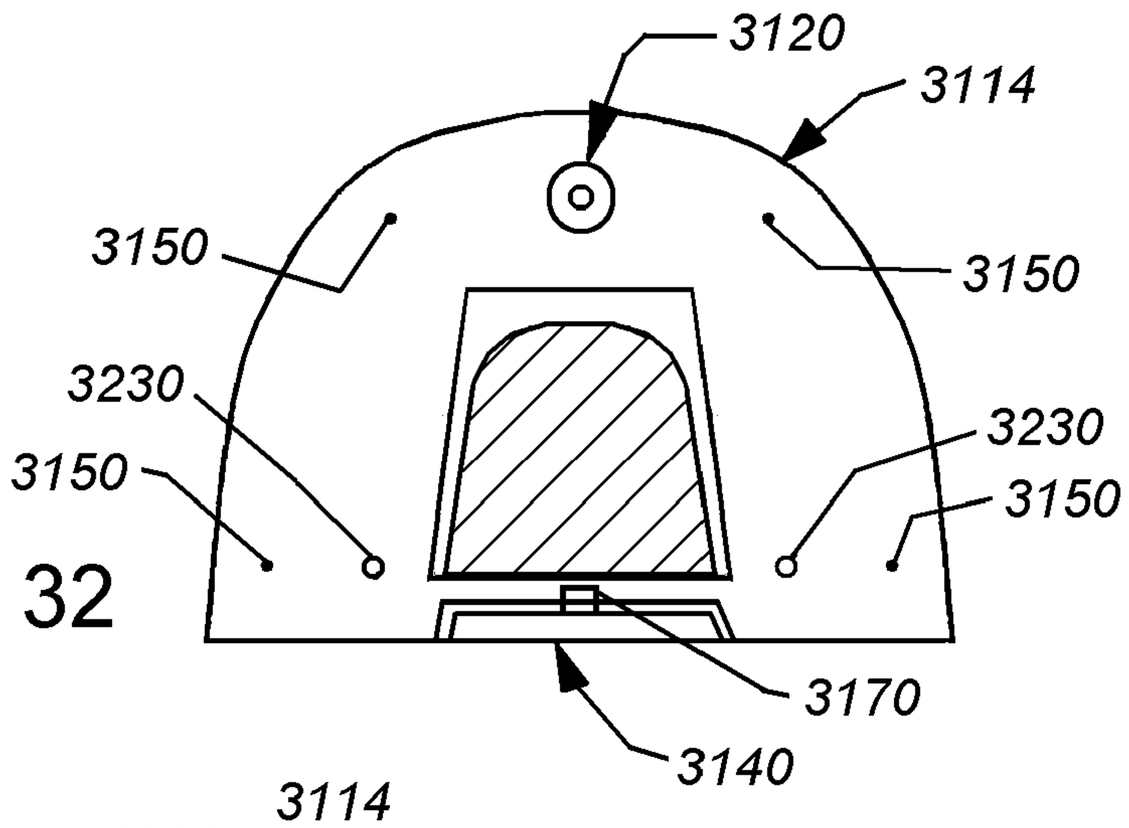

FIG. 32

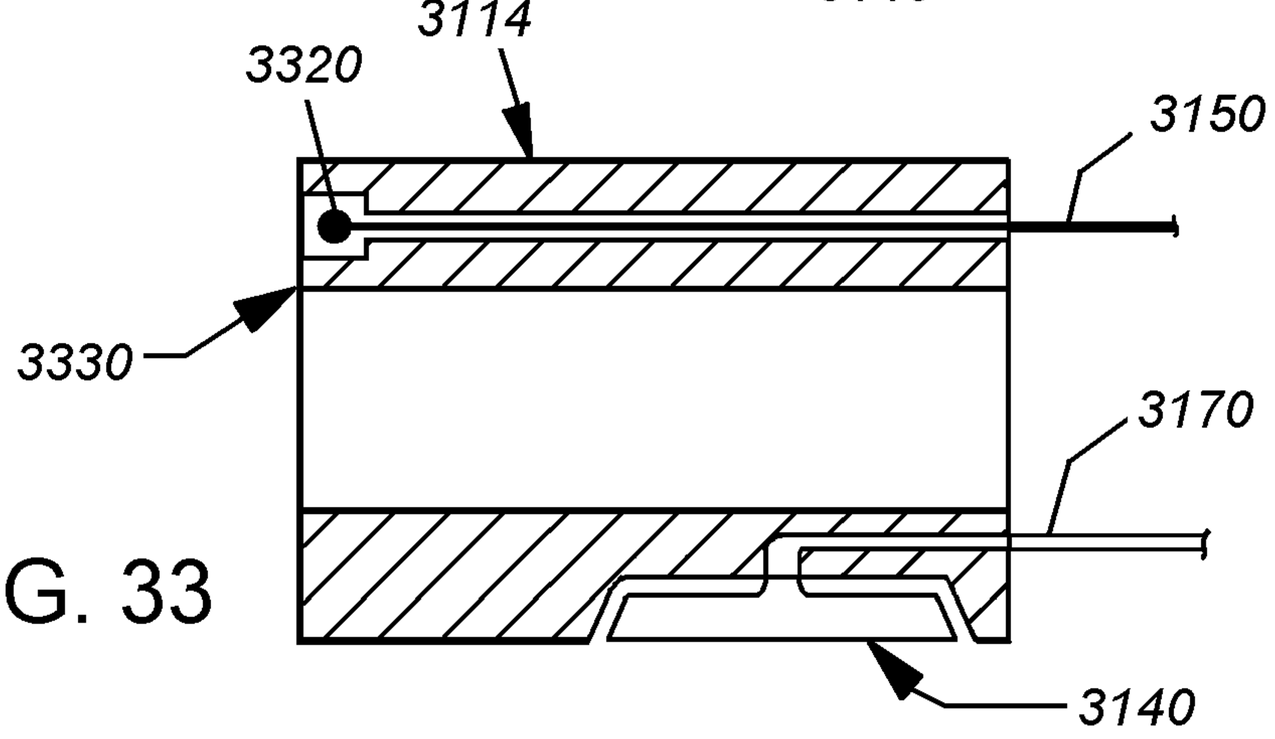

FIG. 33

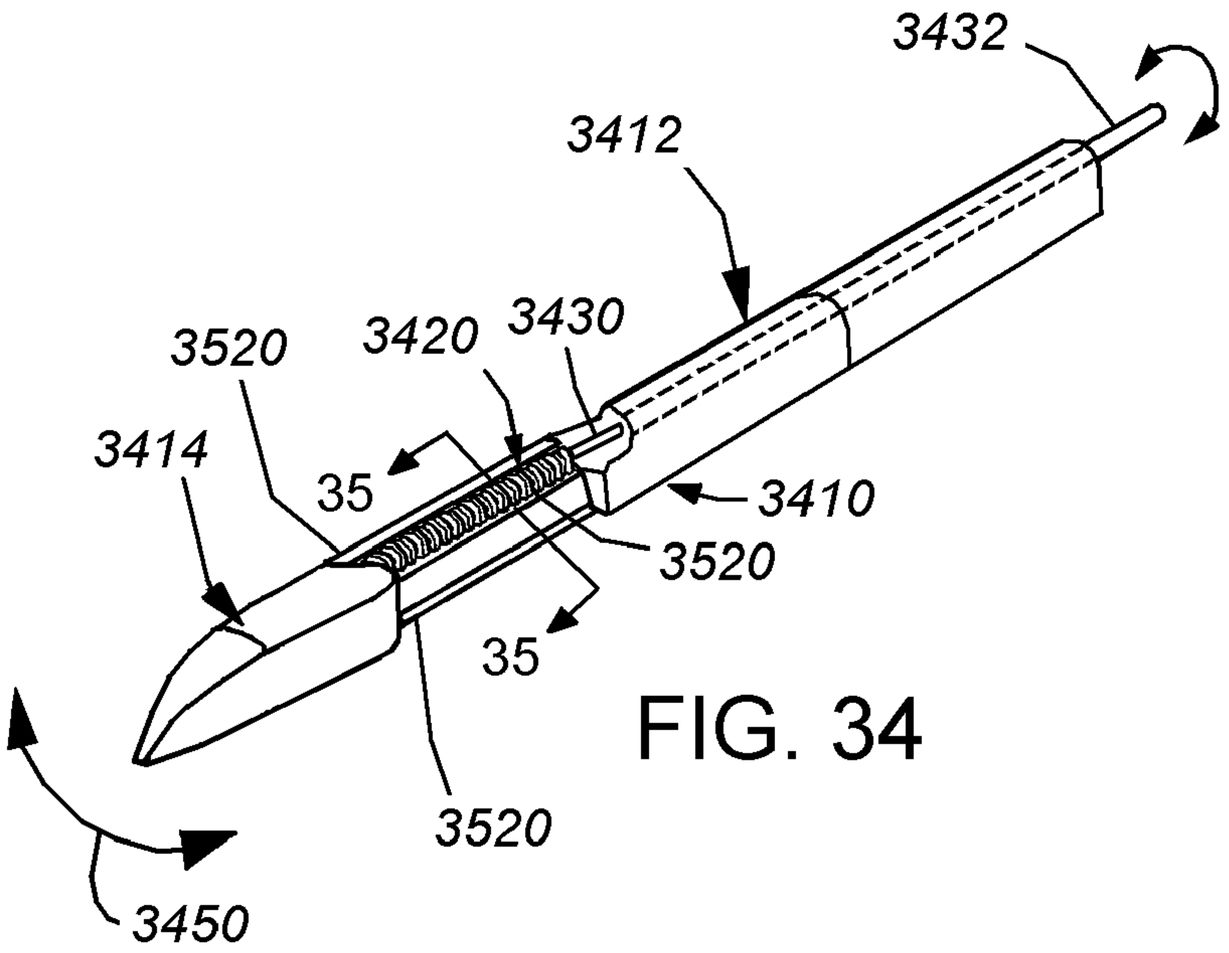
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FIG. 34

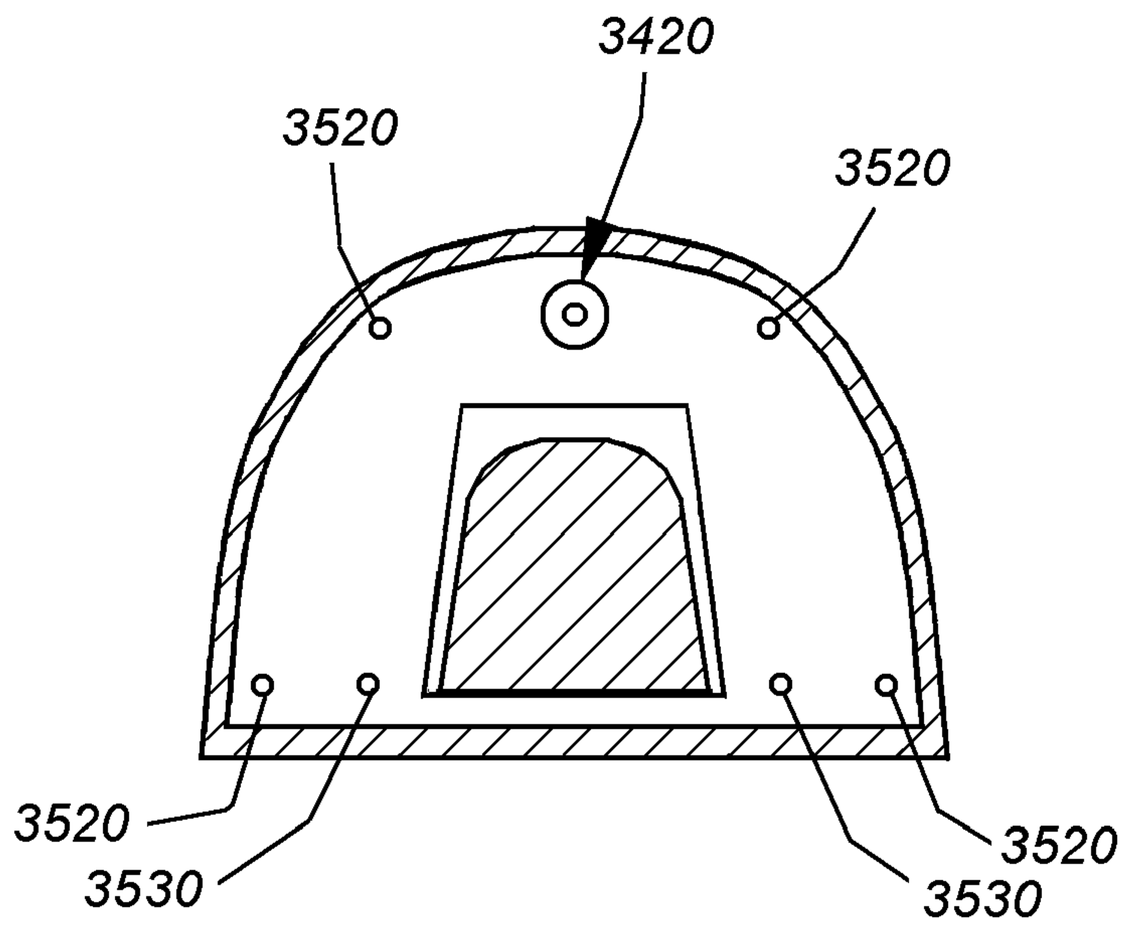
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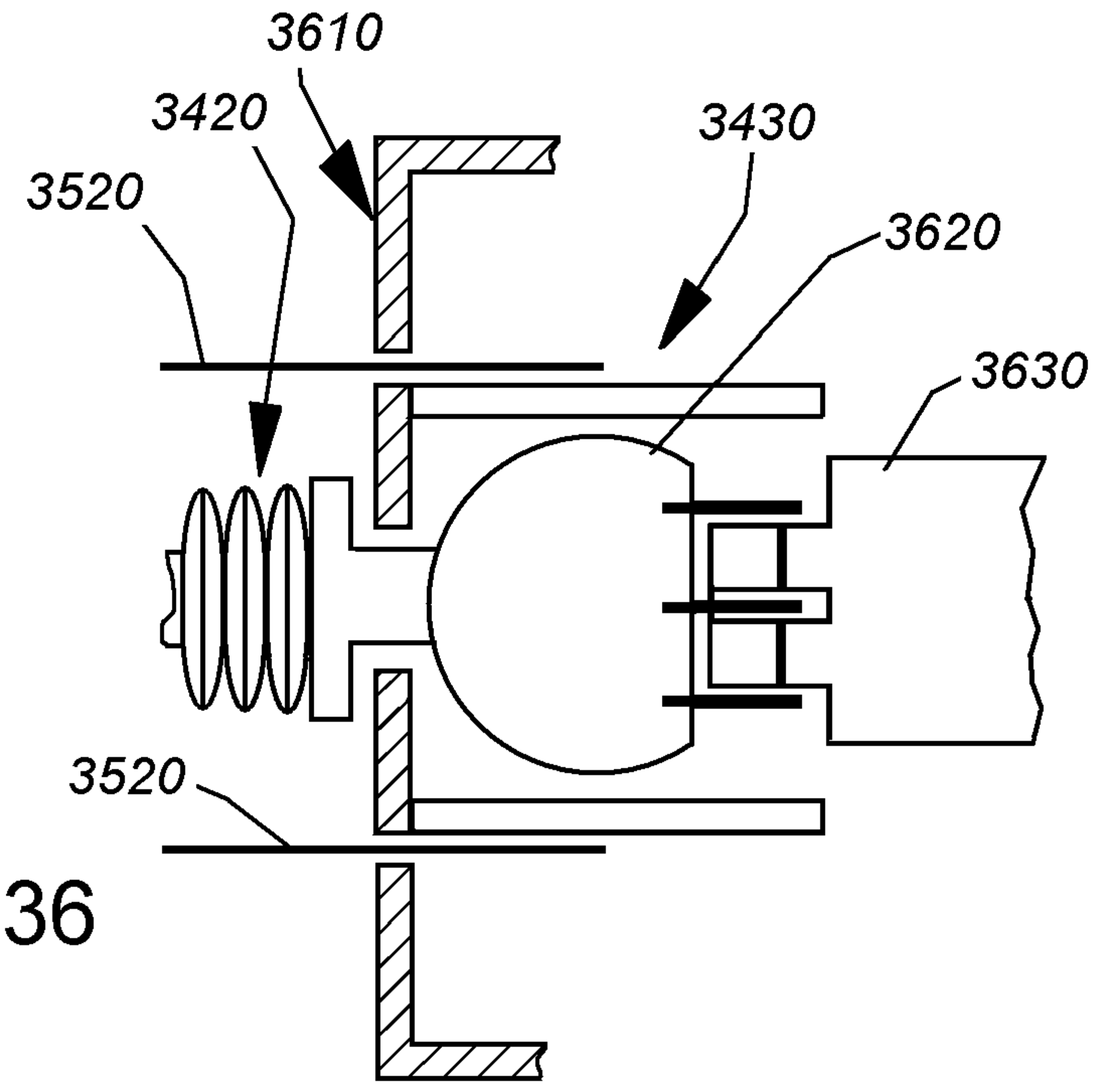
FIG. 35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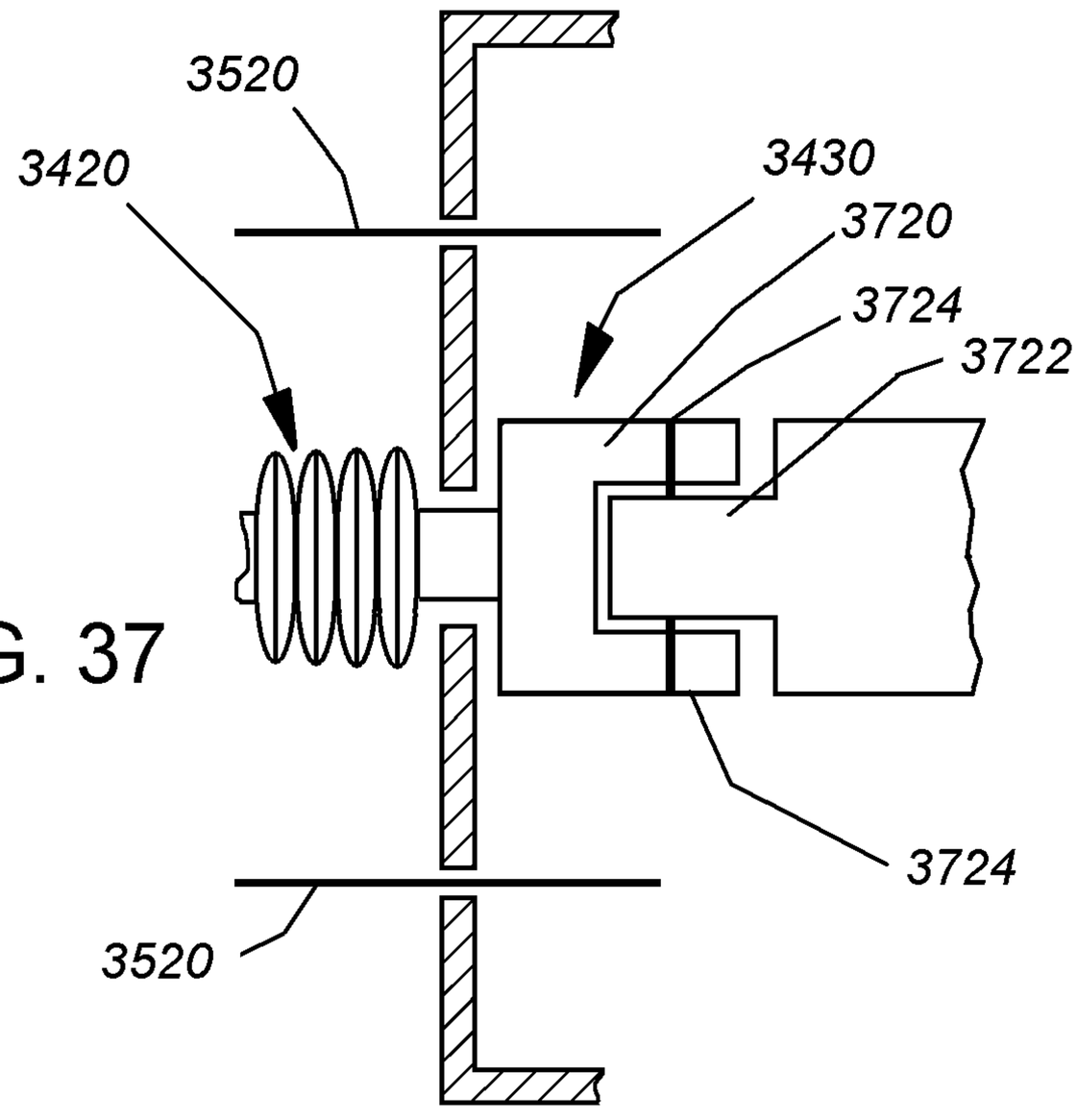
3520

FIG. 36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3724
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FIG. 37

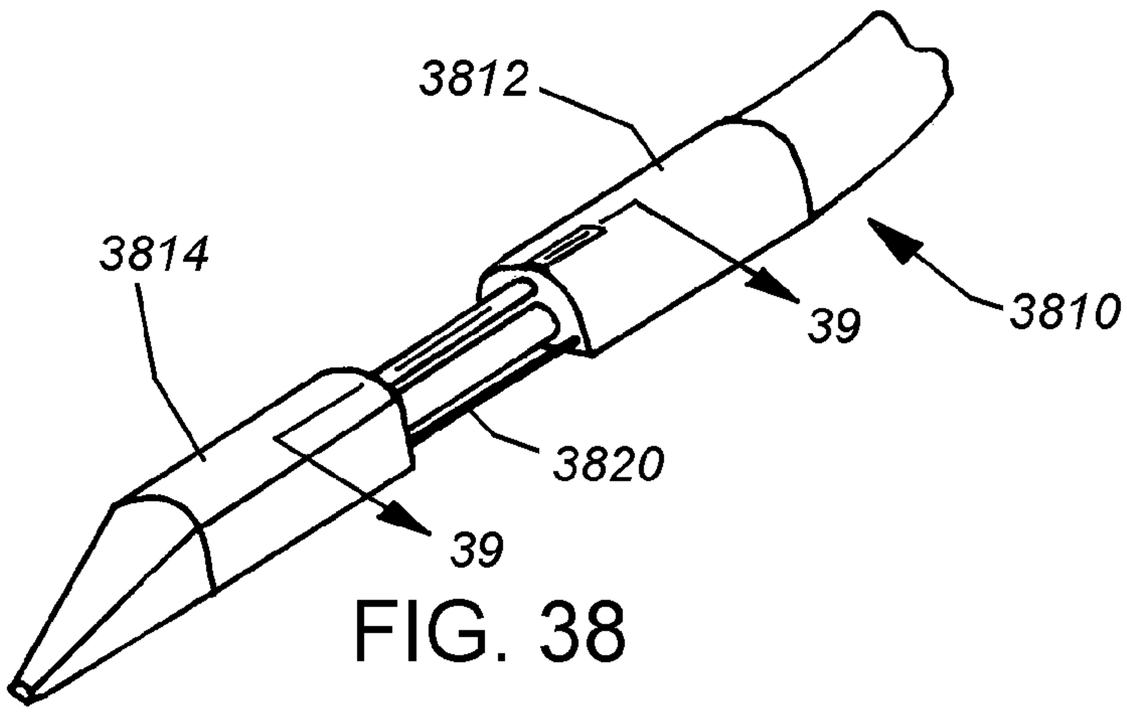
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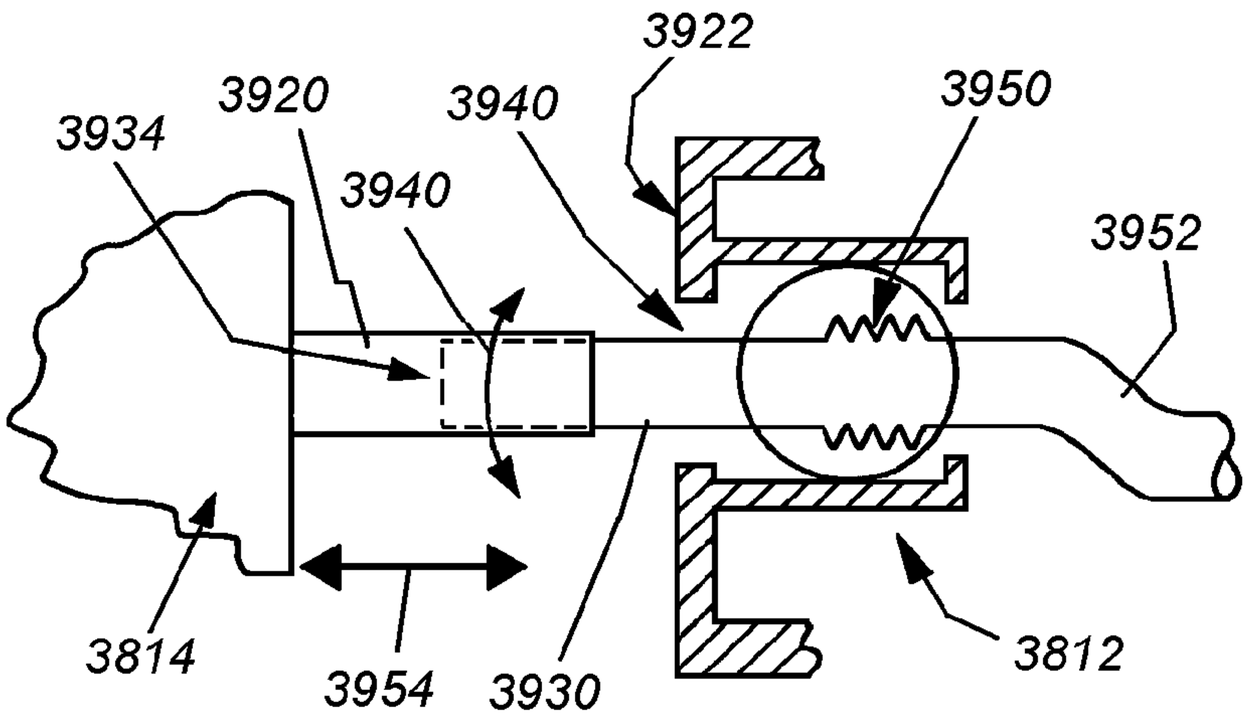
FIG. 38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3930
3812

FIG. 39

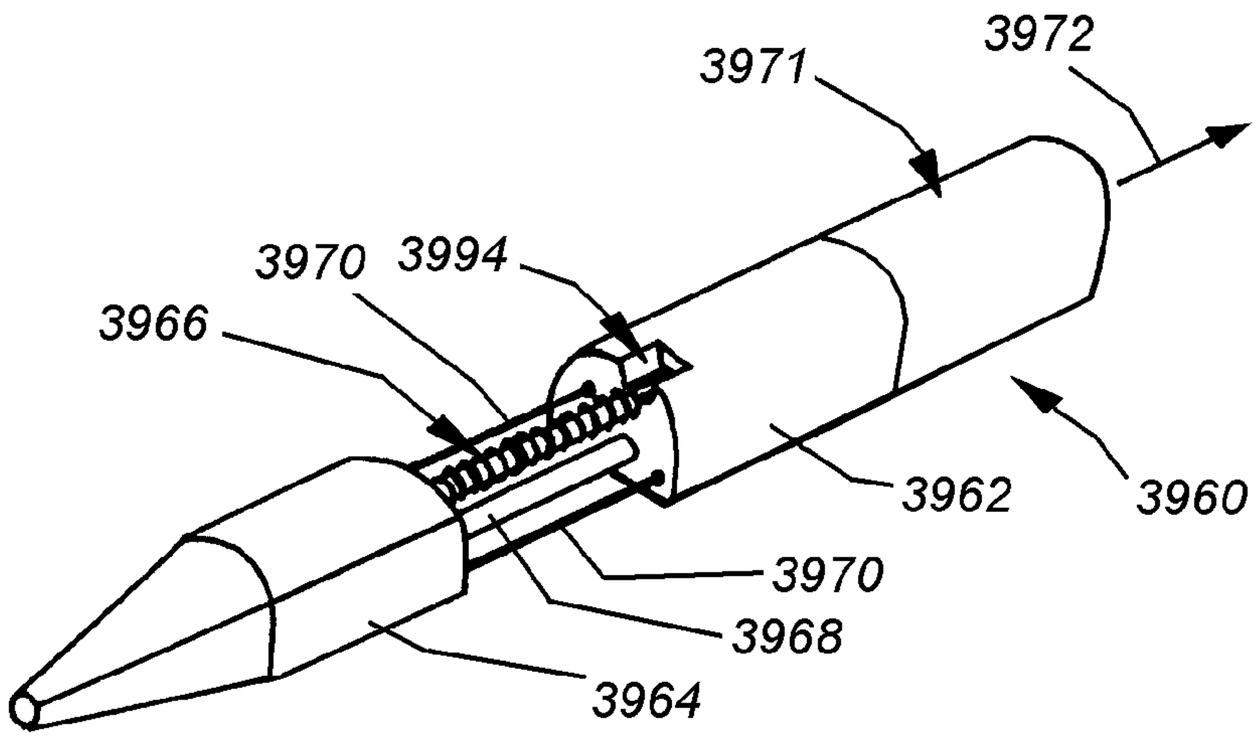


FIG. 39A

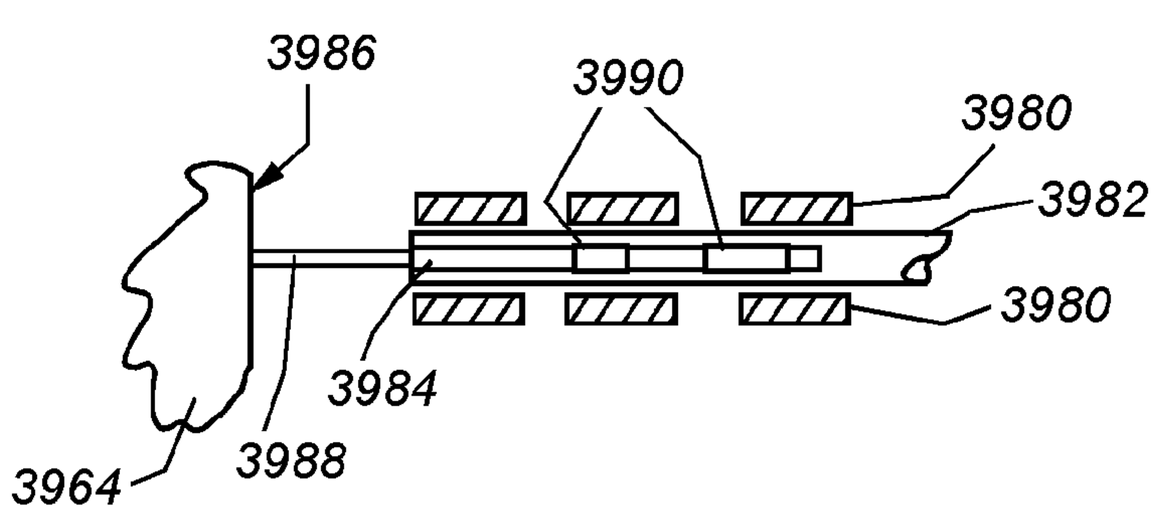
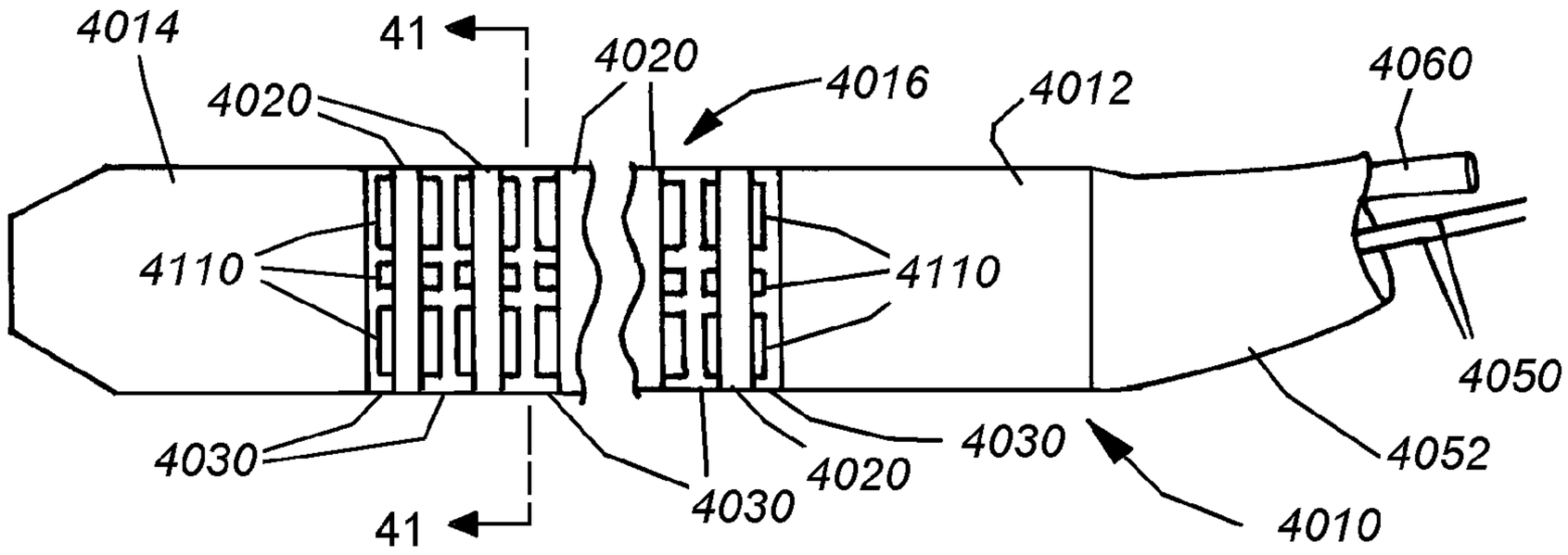


FIG. 39B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41
4020
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4110
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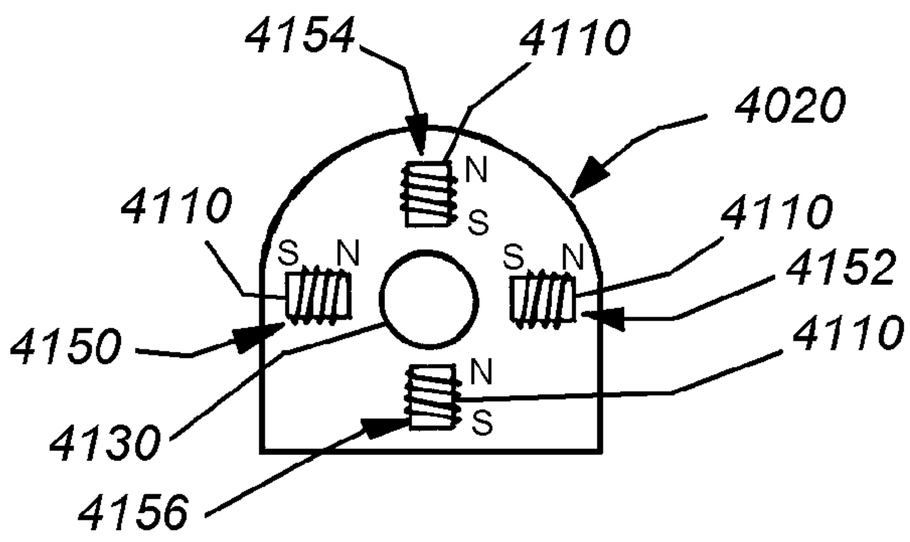
4030
4030
4020
4030
4052
41
4010

FIG. 40


4154
4110
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N
S
4110
4110
S N
S N
4152
4150
4110
N
4130
S
4156

FIG. 41

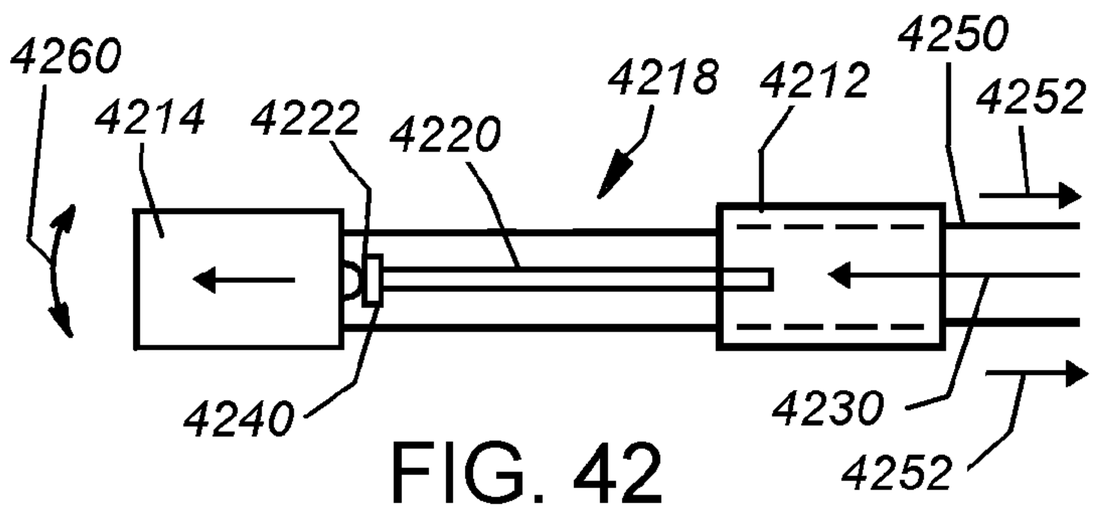


FIG. 42

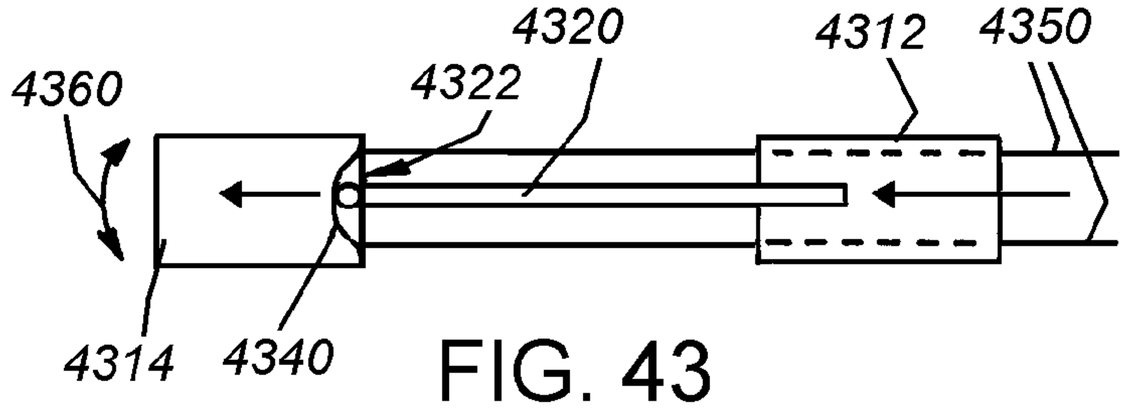


FIG. 43

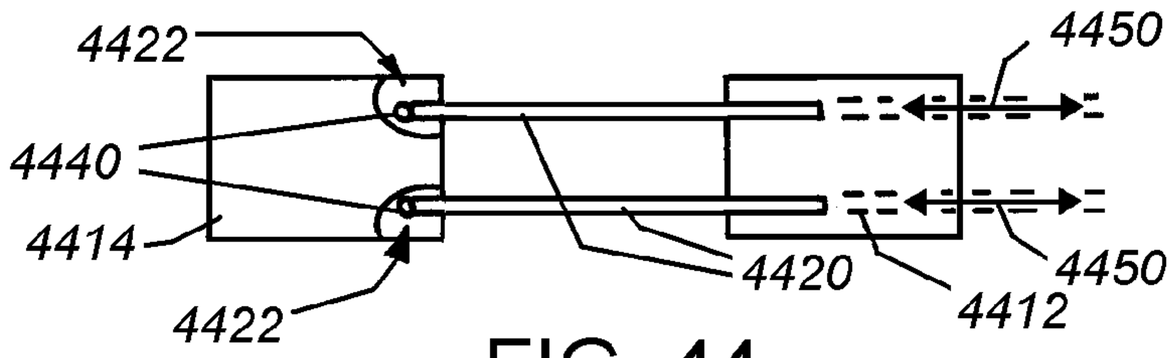


FIG. 44

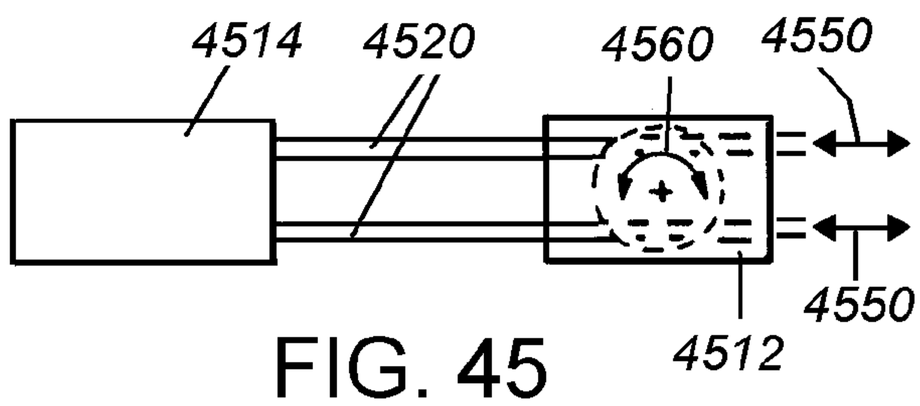


FIG. 45

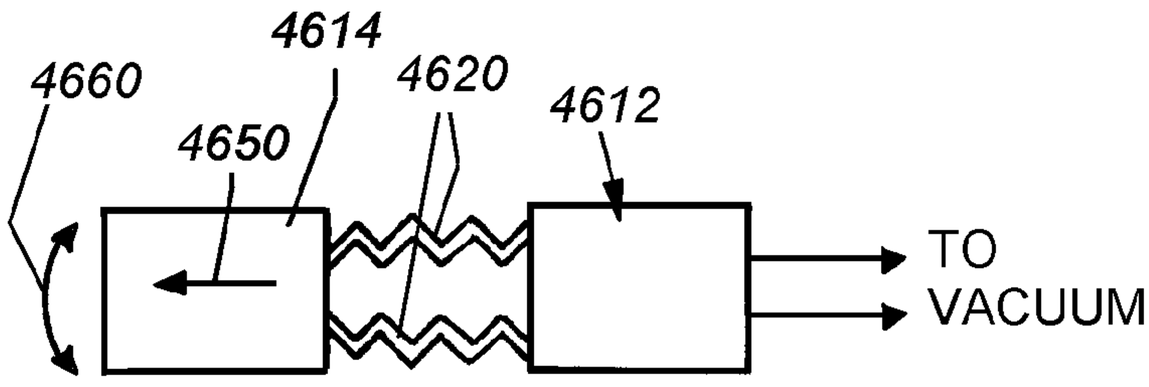


FIG. 46

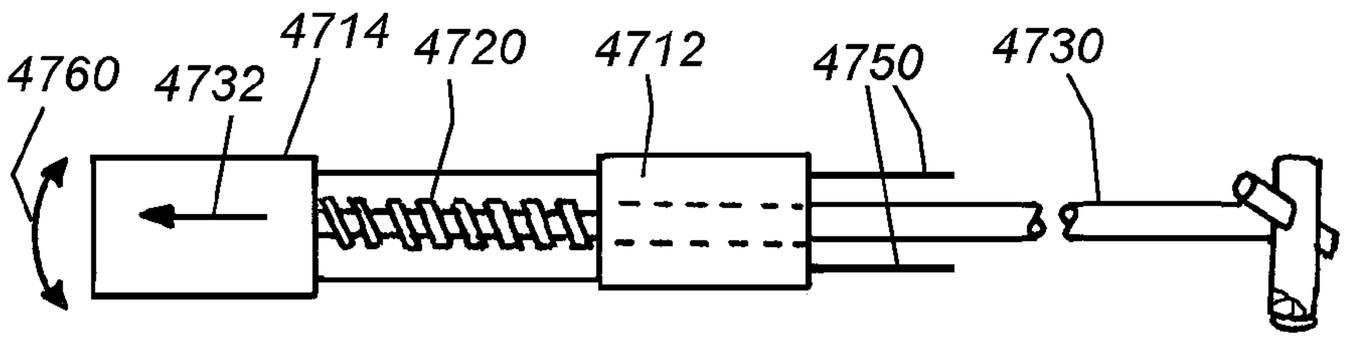


FIG. 47

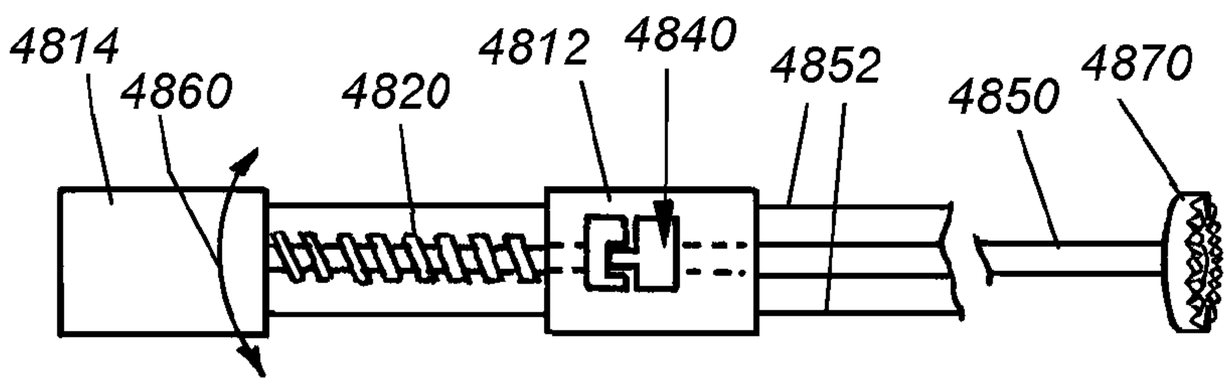


FIG. 48

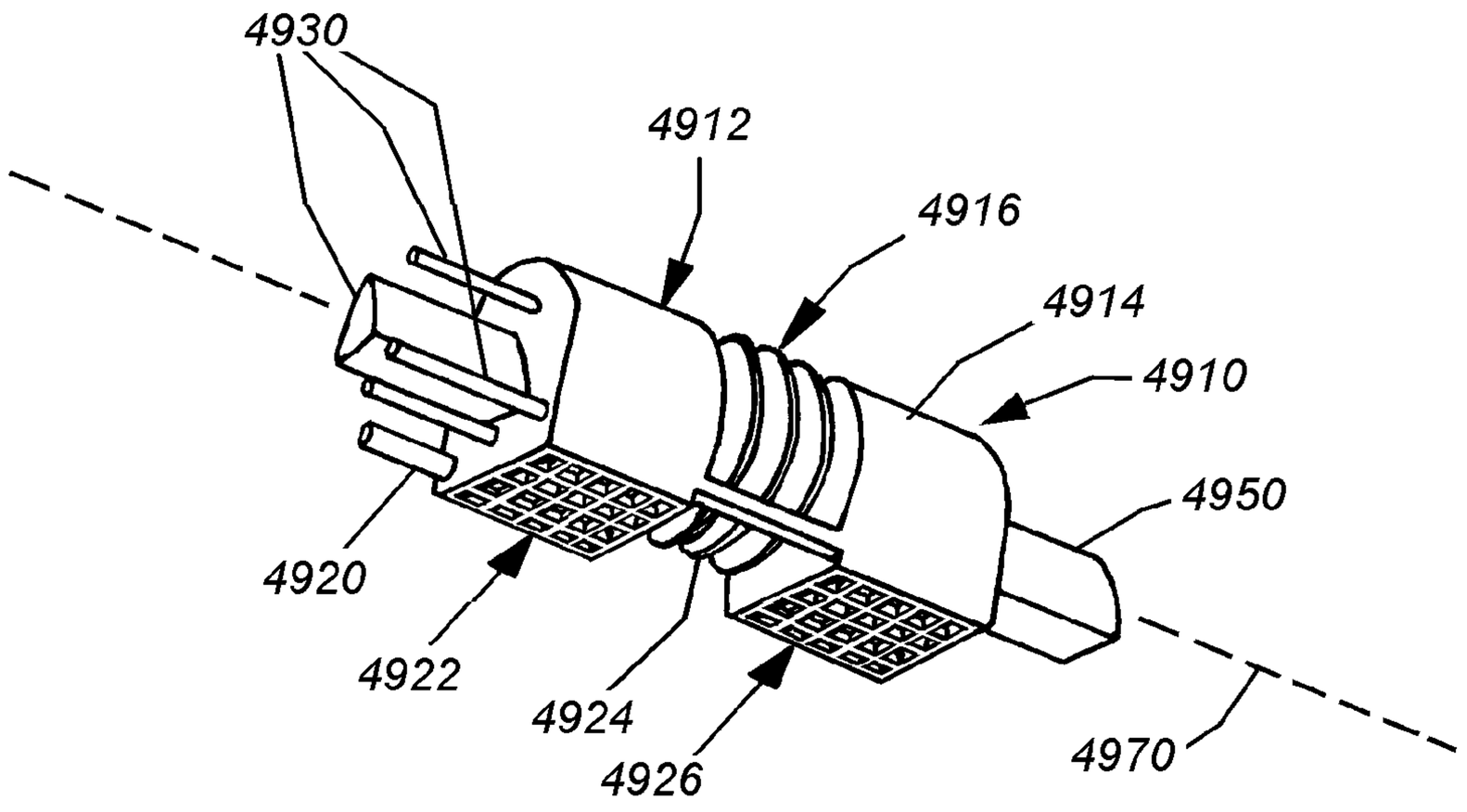


FIG. 49

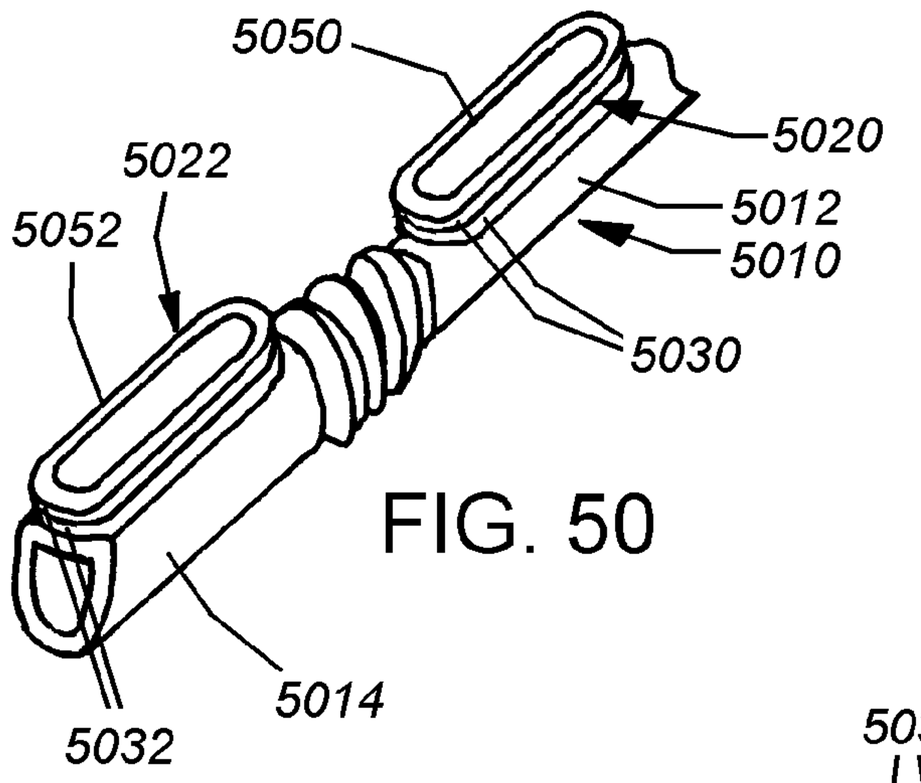


FIG. 50

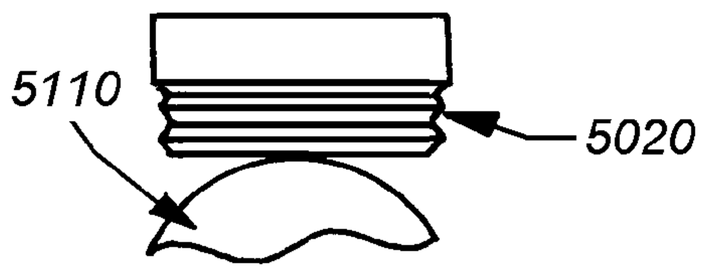


FIG. 51

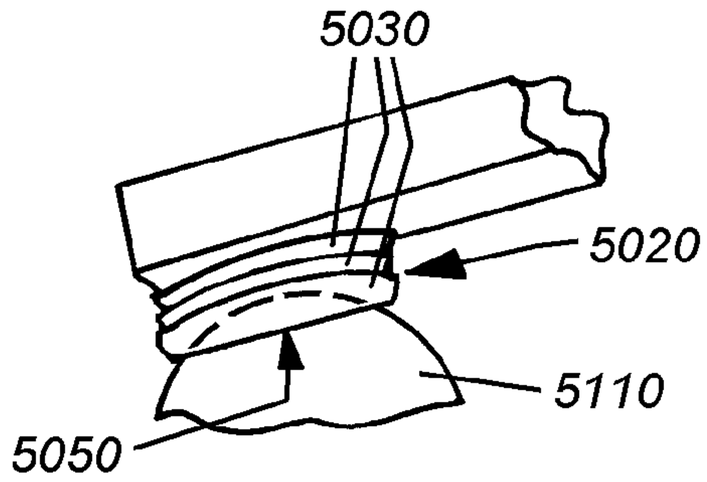


FIG. 52

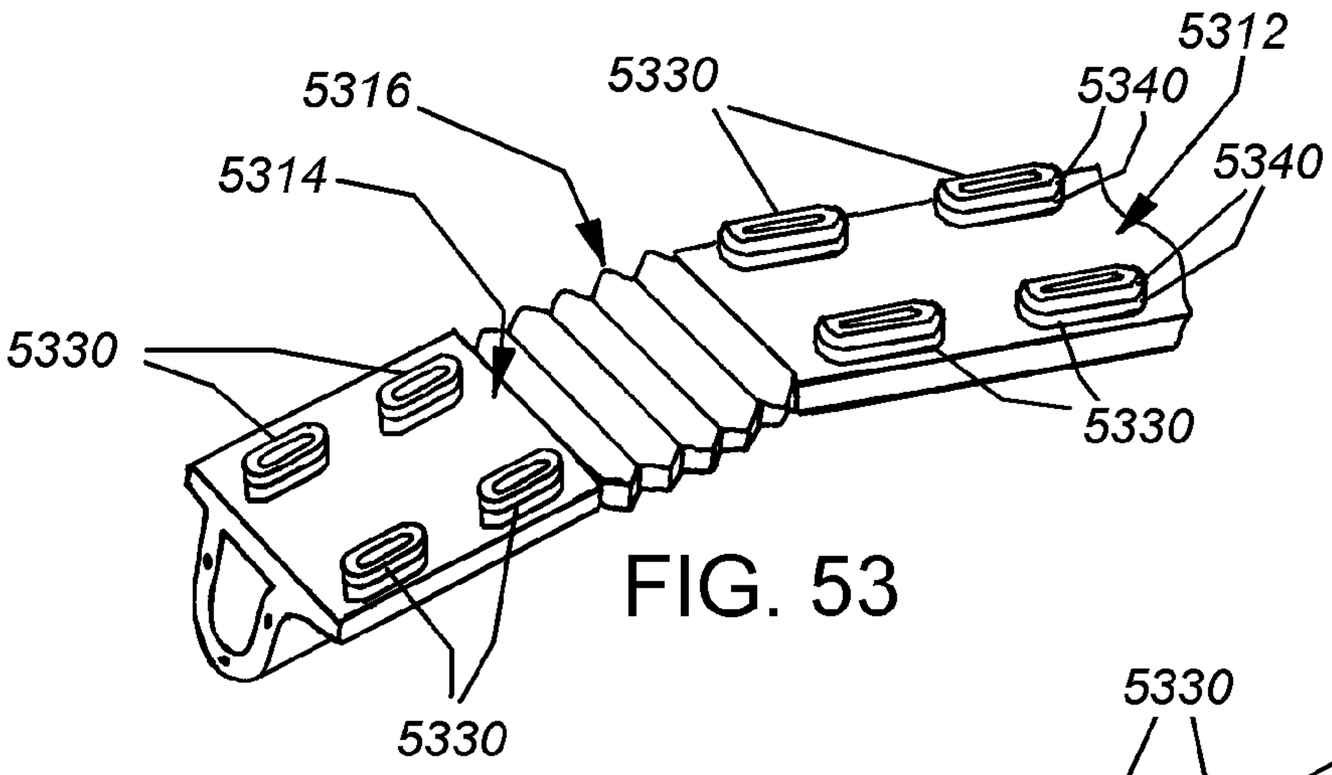


FIG. 53

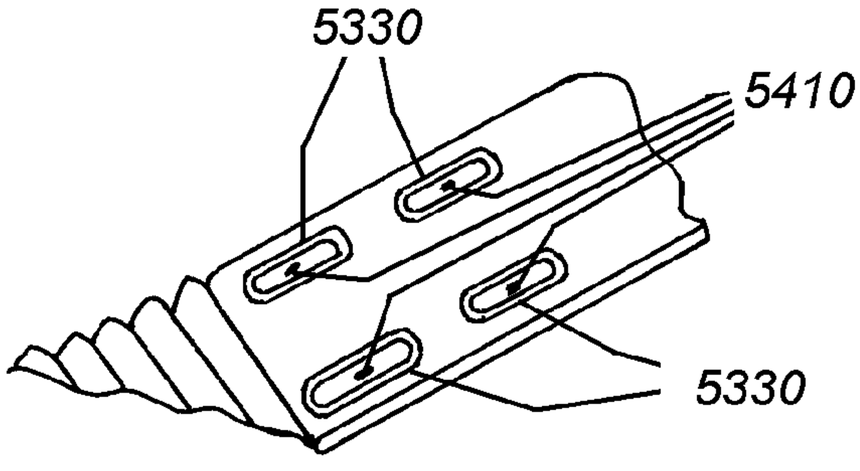


FIG. 54

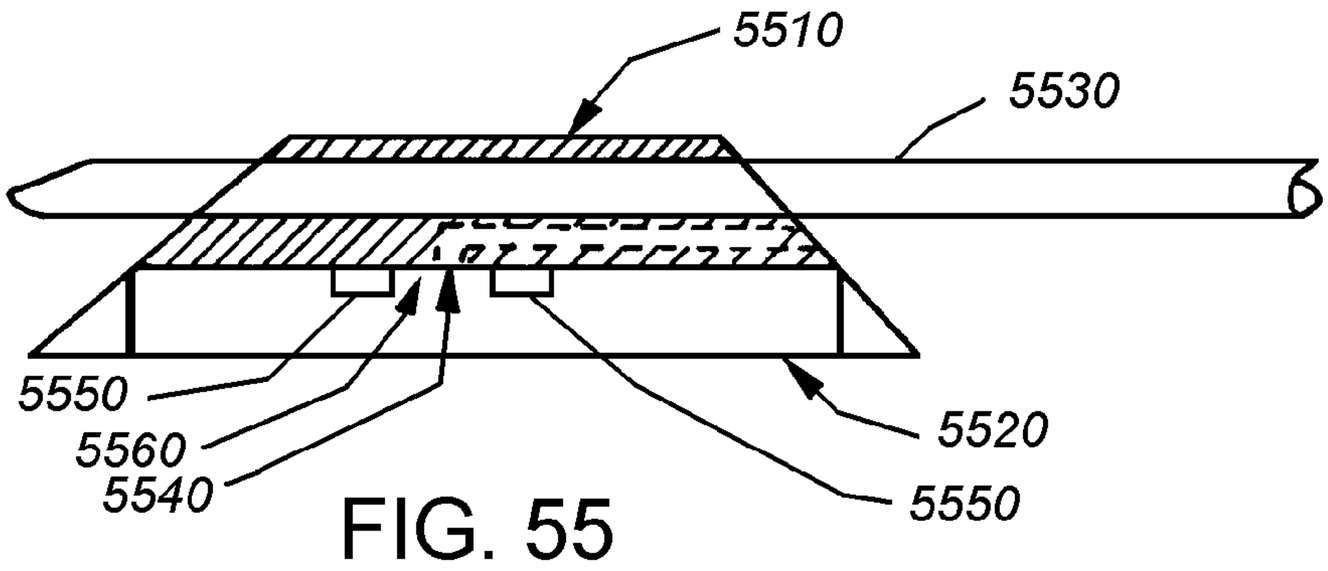


FIG. 55

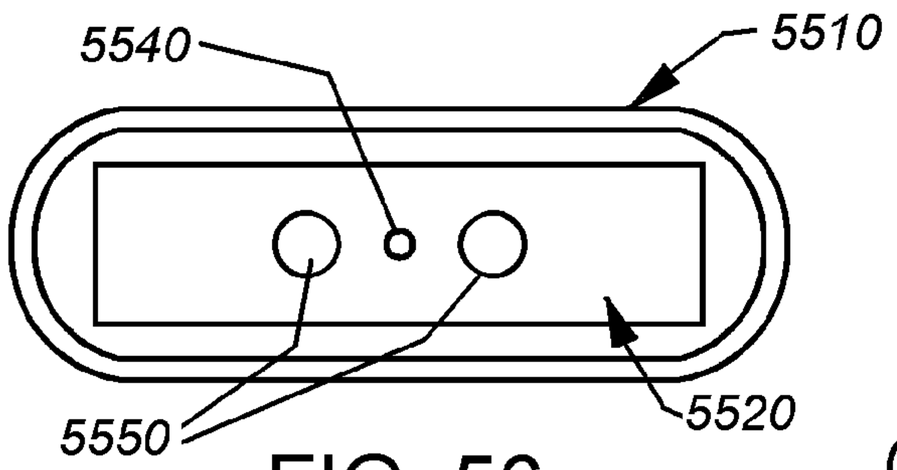


FIG. 56

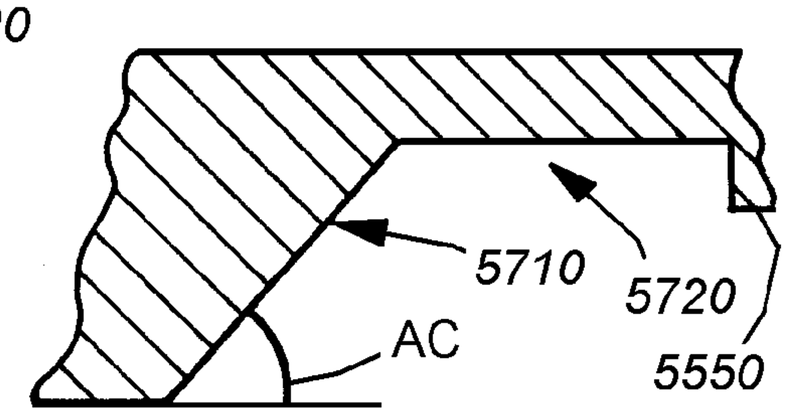


FIG. 57

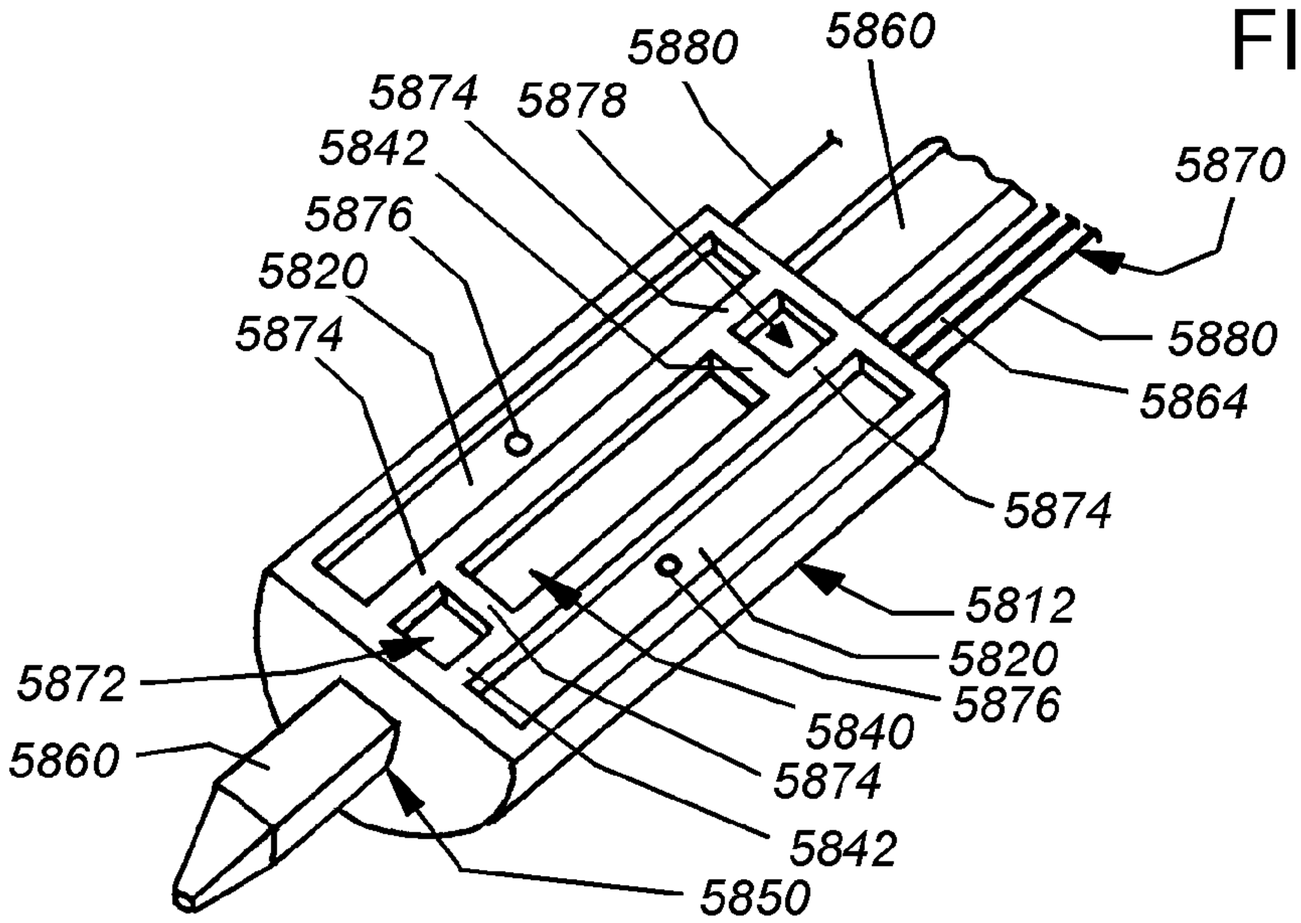
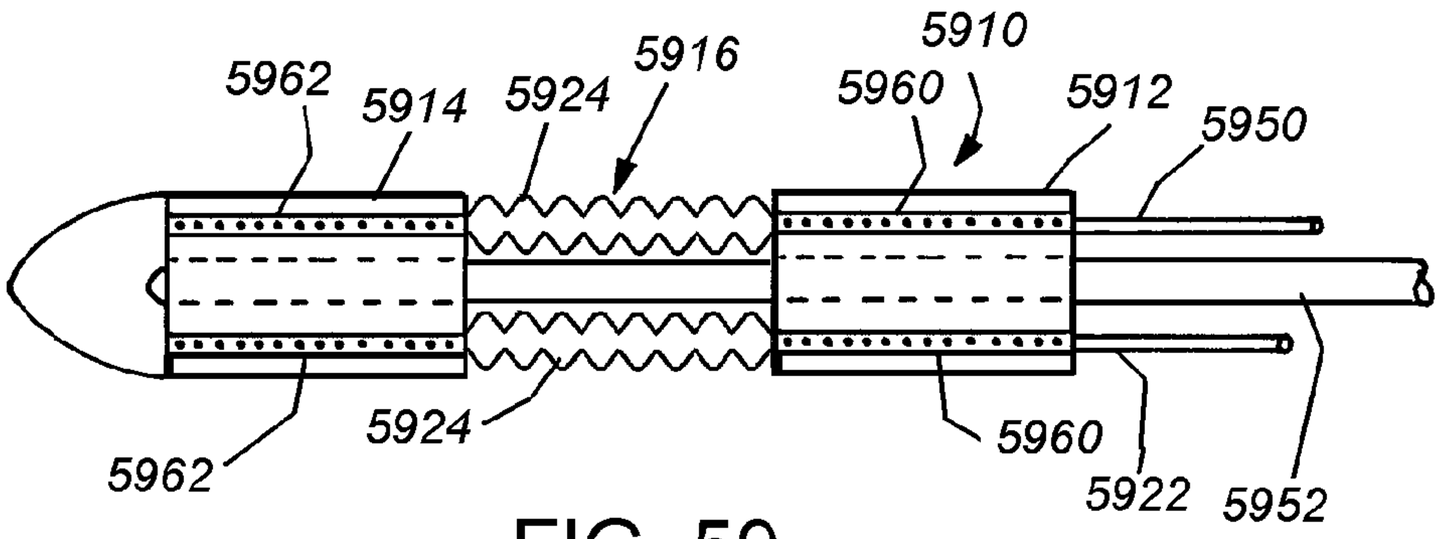


FIG. 58


5962
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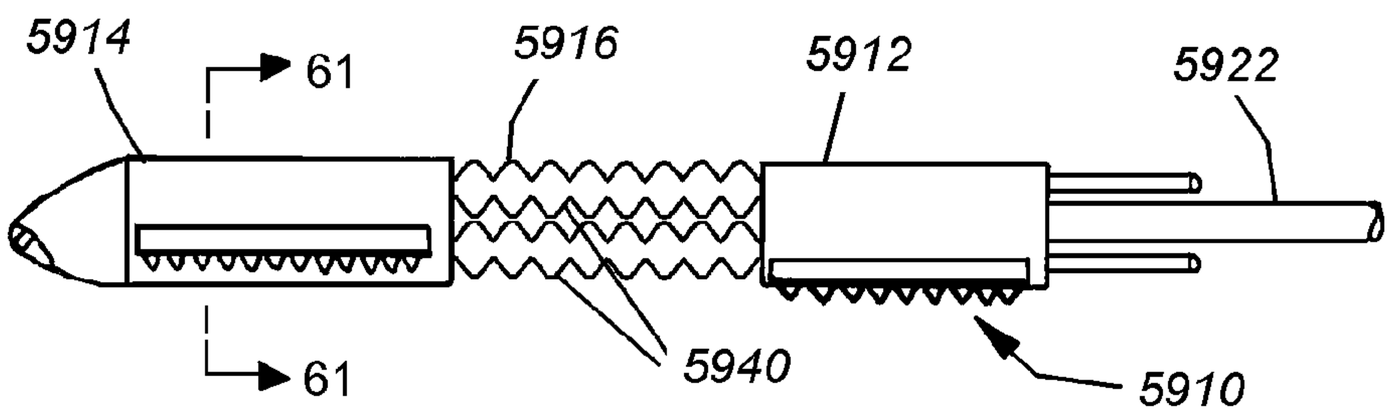
5916
5960
5910
5912
5950
5962
5924
5960
5922
5952

FIG. 59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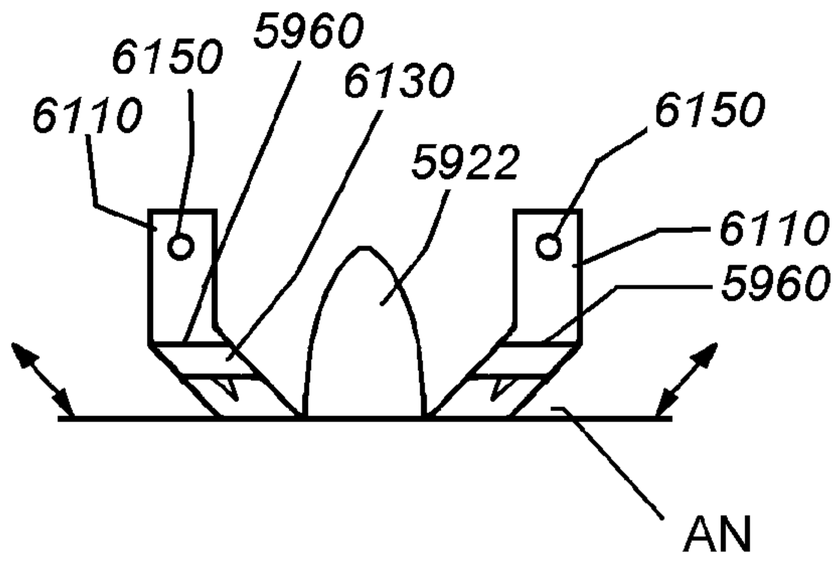
61
5916
5912
5922
61
5940
5910

FIG. 60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5960
6130
6110
5922
6150
6110
5960
AN

FIG. 61

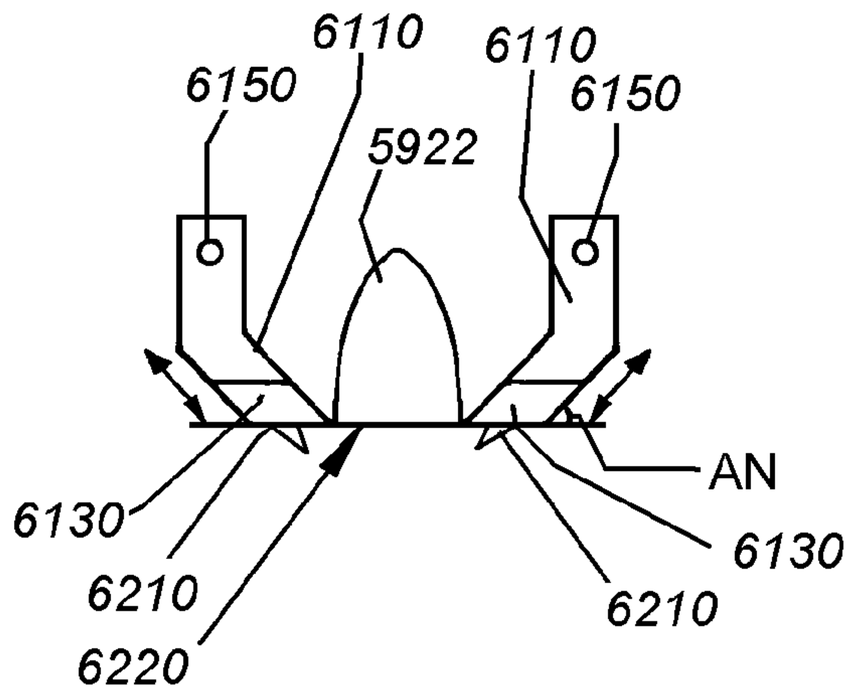

6110
6110
6150
6150
5922
AN
6130
6130
6210
6210
6220

FIG. 62

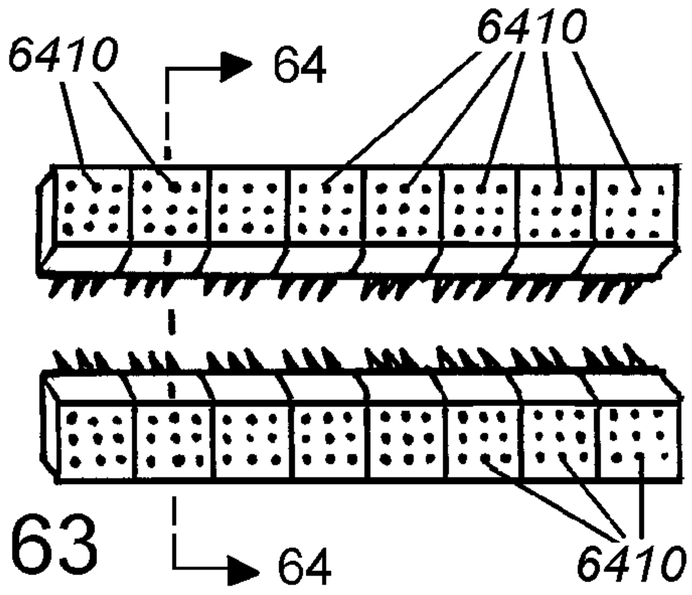


FIG. 63

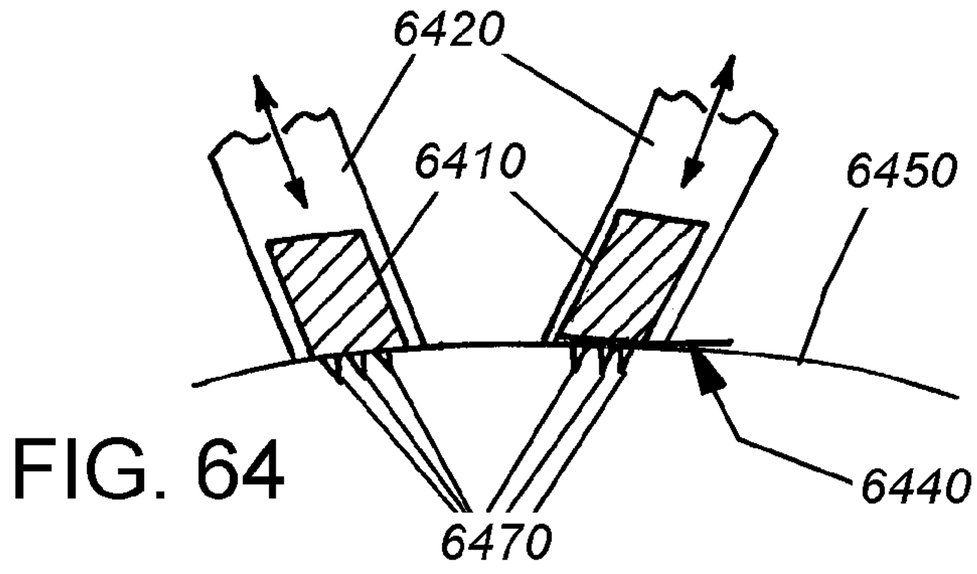


FIG. 64

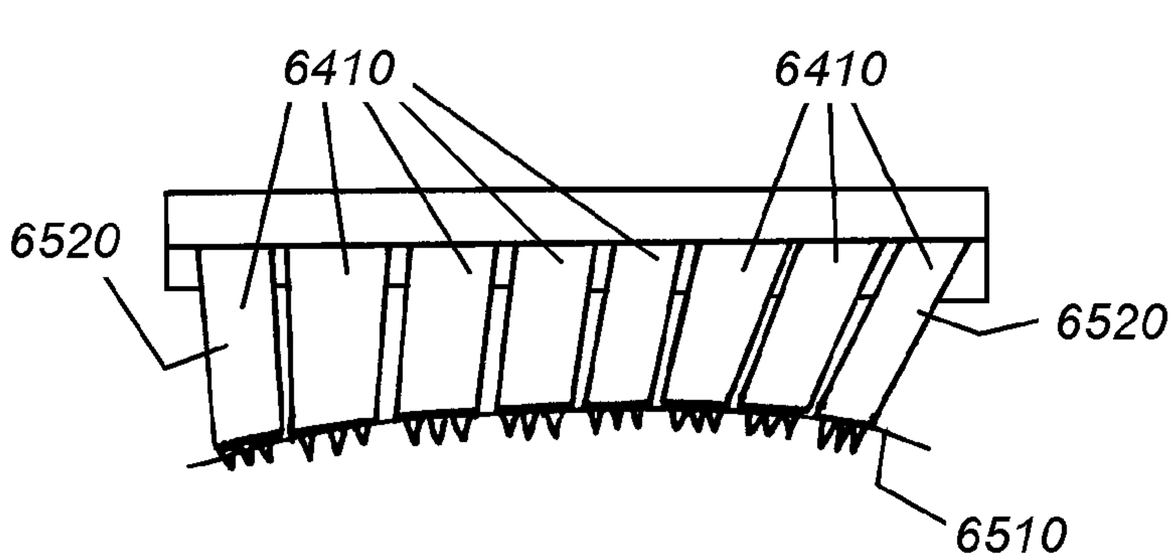


FIG. 65

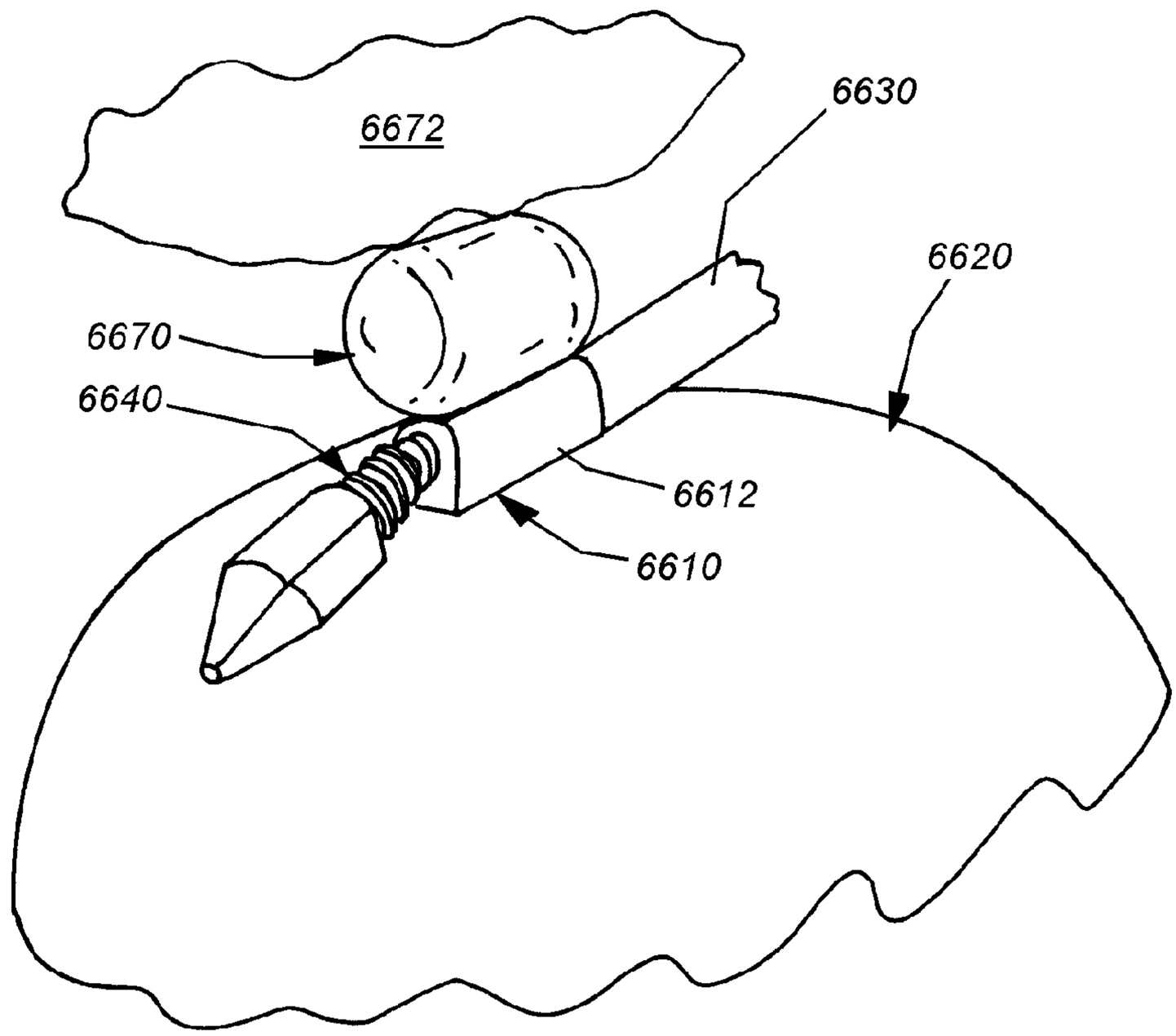


FIG. 66

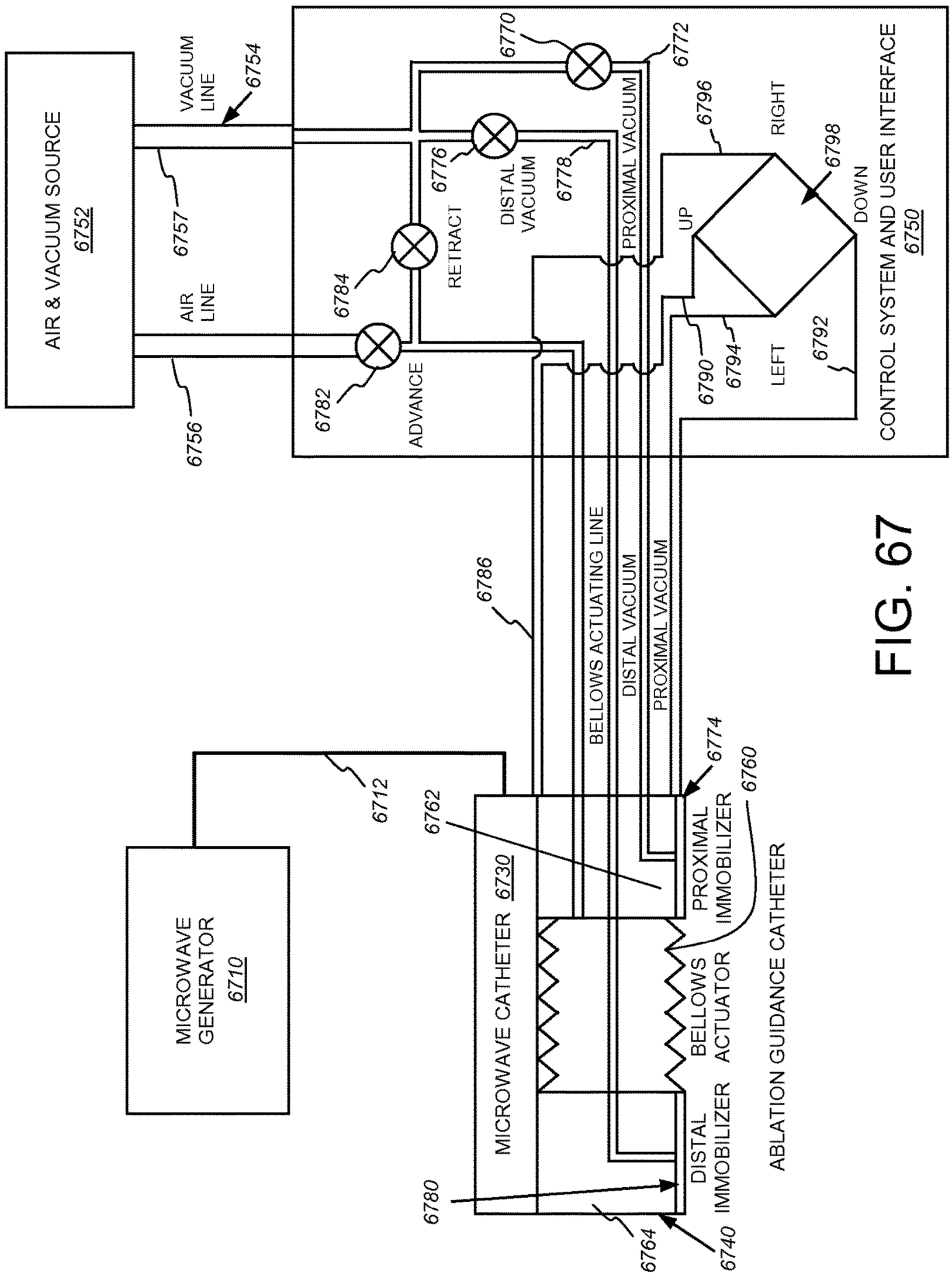

AIR & VACUUM SOURCE
6752
VACUUM LINE
6754
6757
AIR LINE
6756
6770
6772
6776
DISTAL VACUUM
6778
PROXIMAL VACUUM
6784
RETRACT
6782
ADVANCE
6796
RIGHT
6798
UP
DOWN
6790
6794
LEFT
6792
CONTROL SYSTEM AND USER INTERFACE
6750
6786
BELLOWS ACTUATING LINE
DISTAL VACUUM
PROXIMAL VACUUM
6712
6762
6774
6760
MICROWAVE GENERATOR
6710
MICROWAVE CATHETER 6730
PROXIMAL IMMOBILIZER
BELLOWS ACTUATOR
DISTAL IMMOBILIZER
6780
6764
6740
ABLATION GUIDANCE CATHETER

FIG. 67

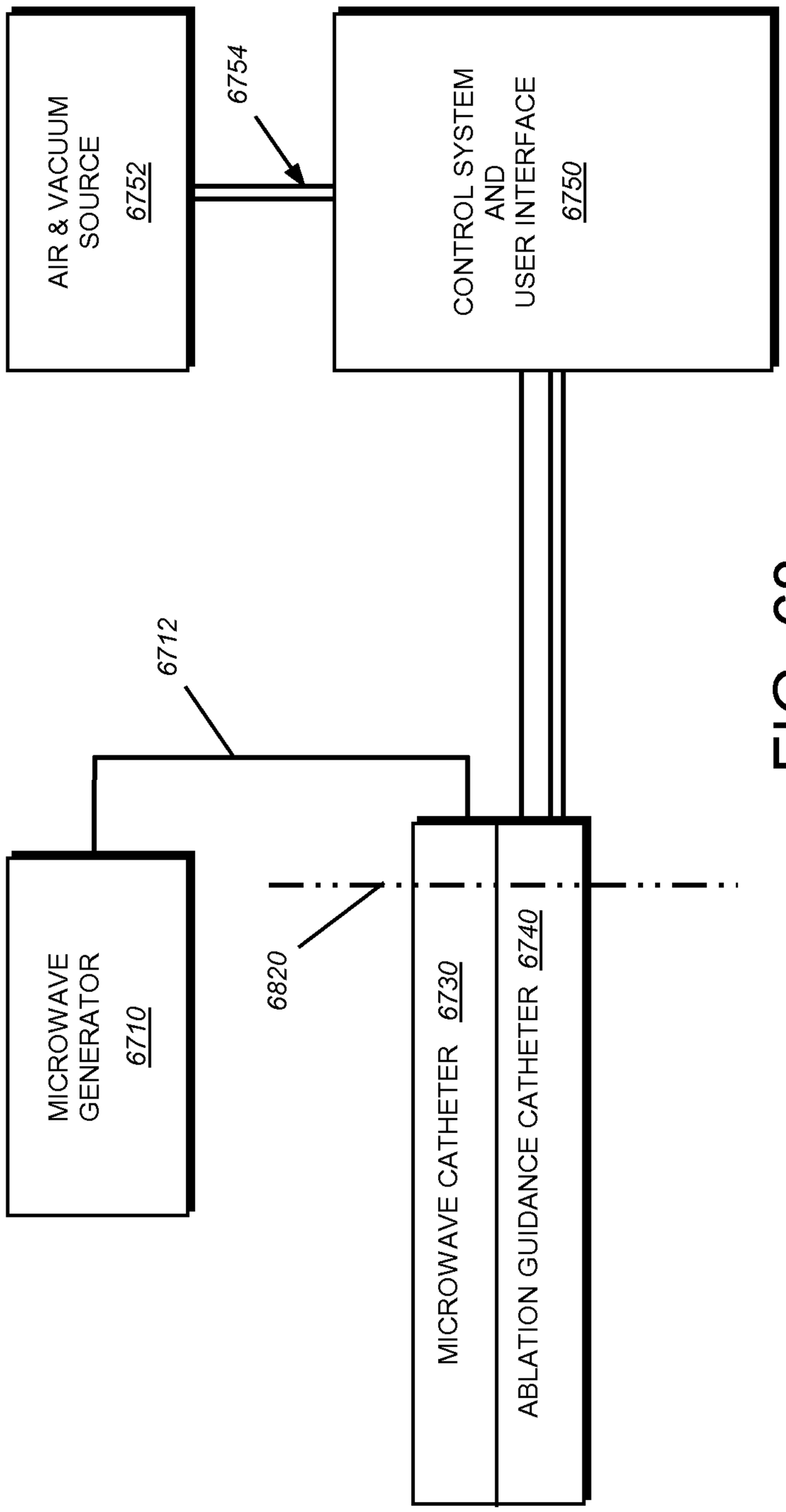
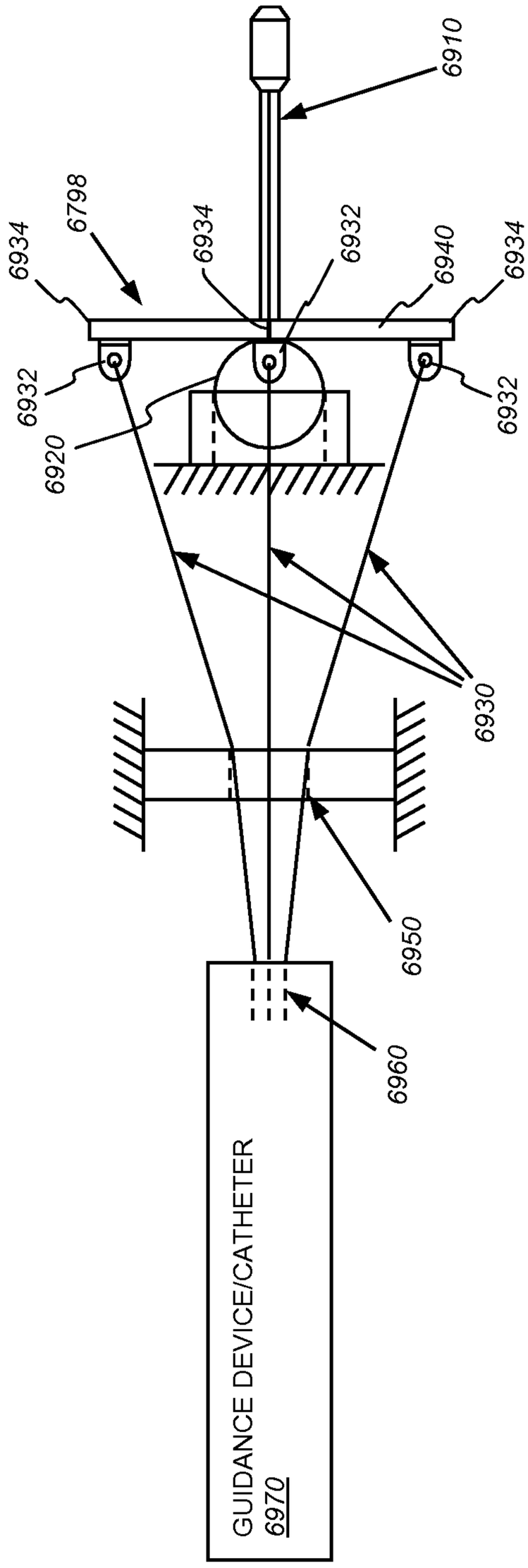

AIR & VACUUM SOURCE 6752
6754
CONTROL SYSTEM AND USER INTERFACE 6750
6712
MICROWAVE GENERATOR 6710
6820
MICROWAVE CATHETER 6730
ABLATION GUIDANCE CATHETER 6740

FIG. 68


6910
6798
6934
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6932
6940
6934
6932
6920
6932
6930
6950
6960
GUIDANCE DEVICE/CATHETER
6970

FIG. 69

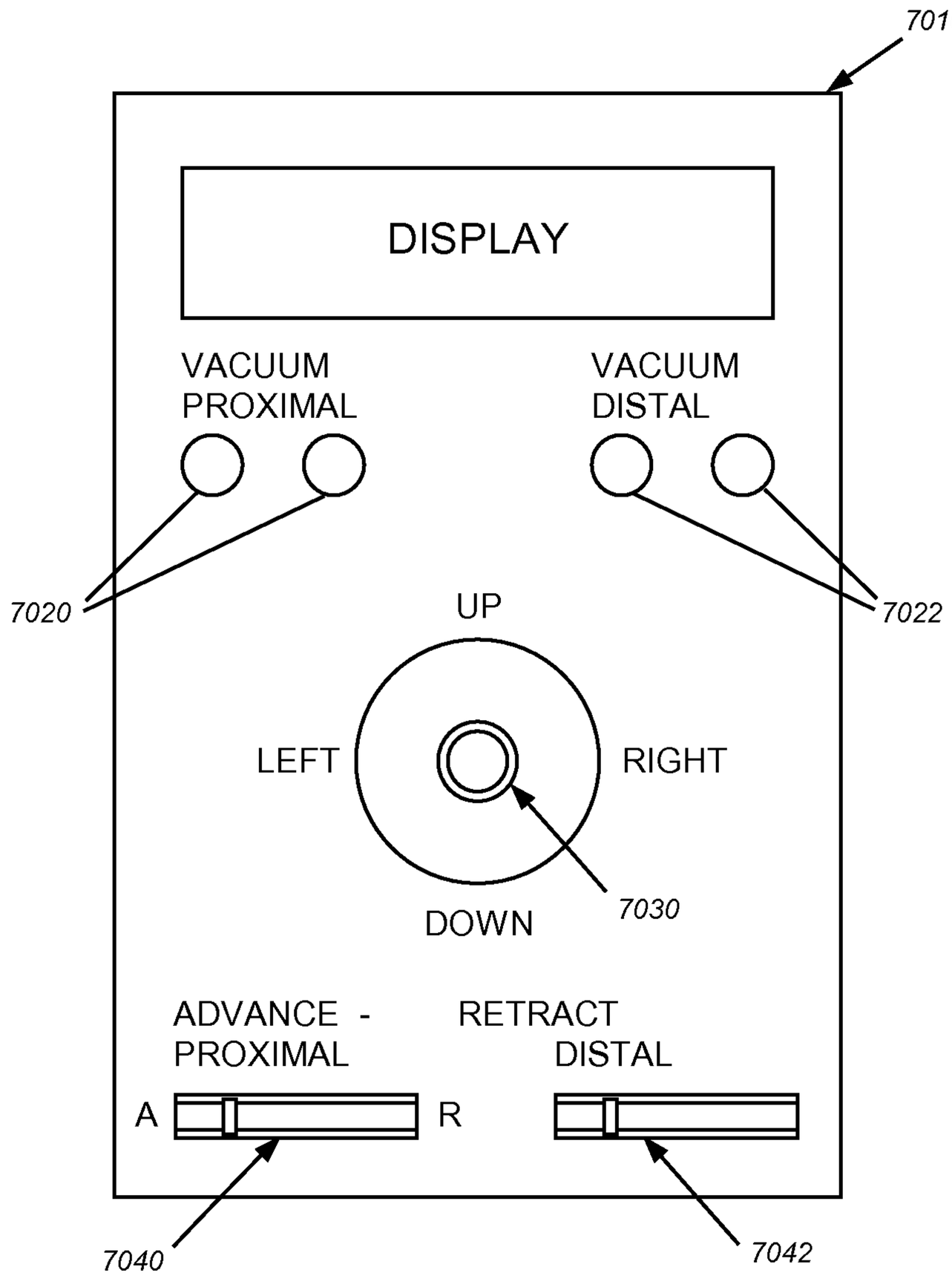
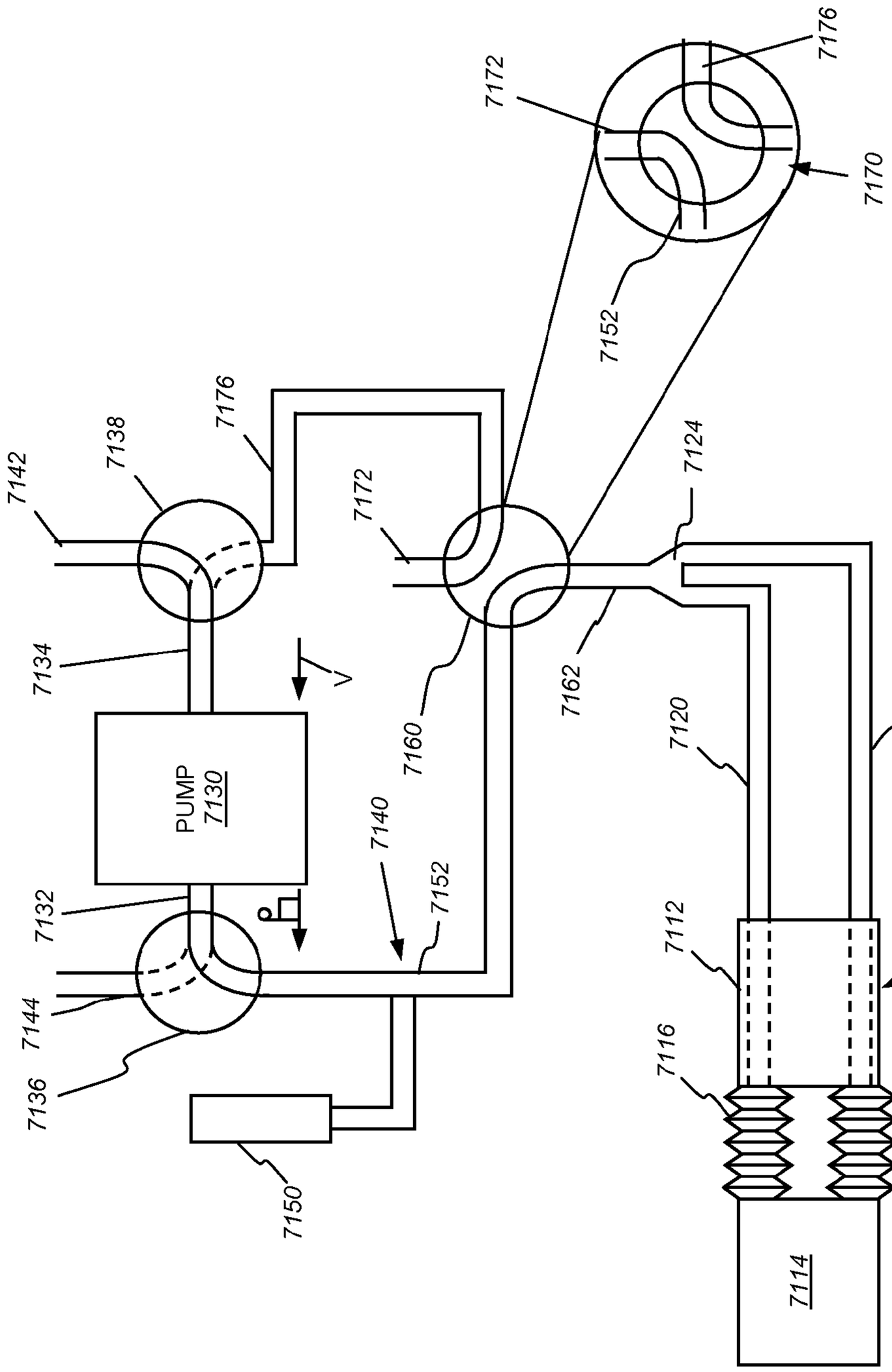

7010
DISPLAY
VACUUM PROXIMAL
VACUUM DISTAL
7020
7022
UP
LEFT
RIGHT
DOWN
7030
ADVANCE - PROXIMAL
RETRACT DISTAL
A
R
7040
7042

FIG. 70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7172
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7134
PUMP
7130
7140
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7162
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7122
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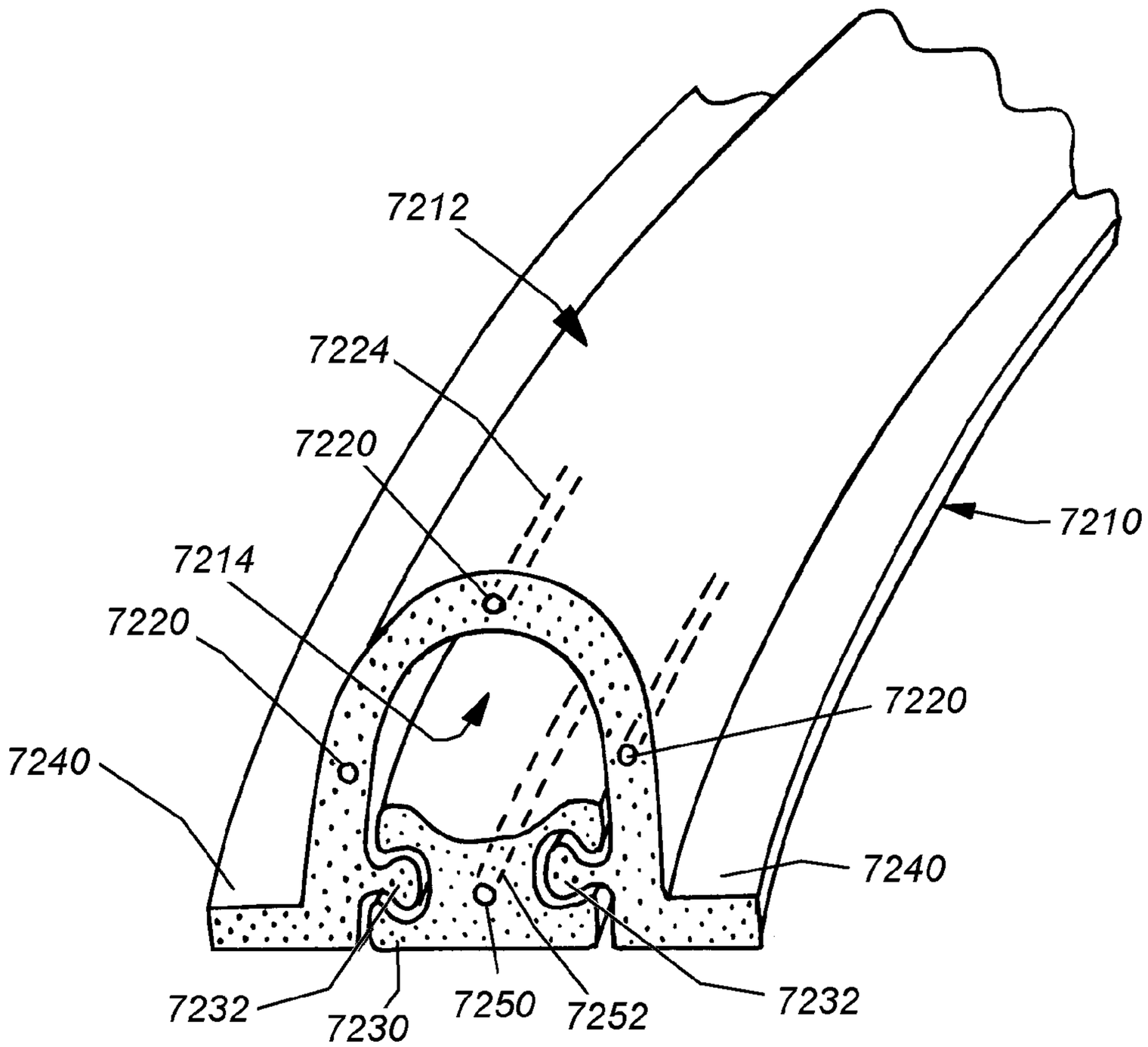
7152
7112
7110
7144
7116
7116
7136
7150
7114

FIG. 71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7232
7230
7250
7252
7232
7220
7240
7210

FIG. 72

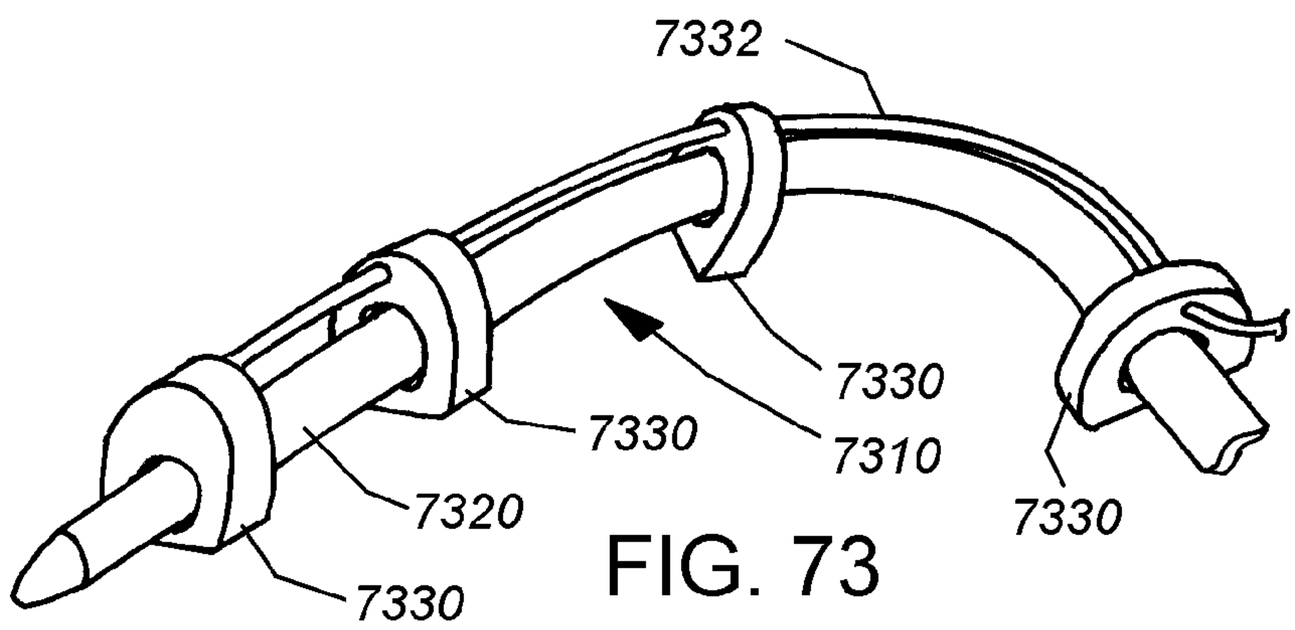

FIG. 73

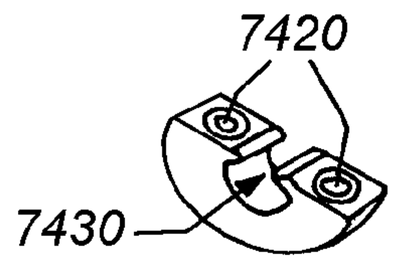

FIG. 74

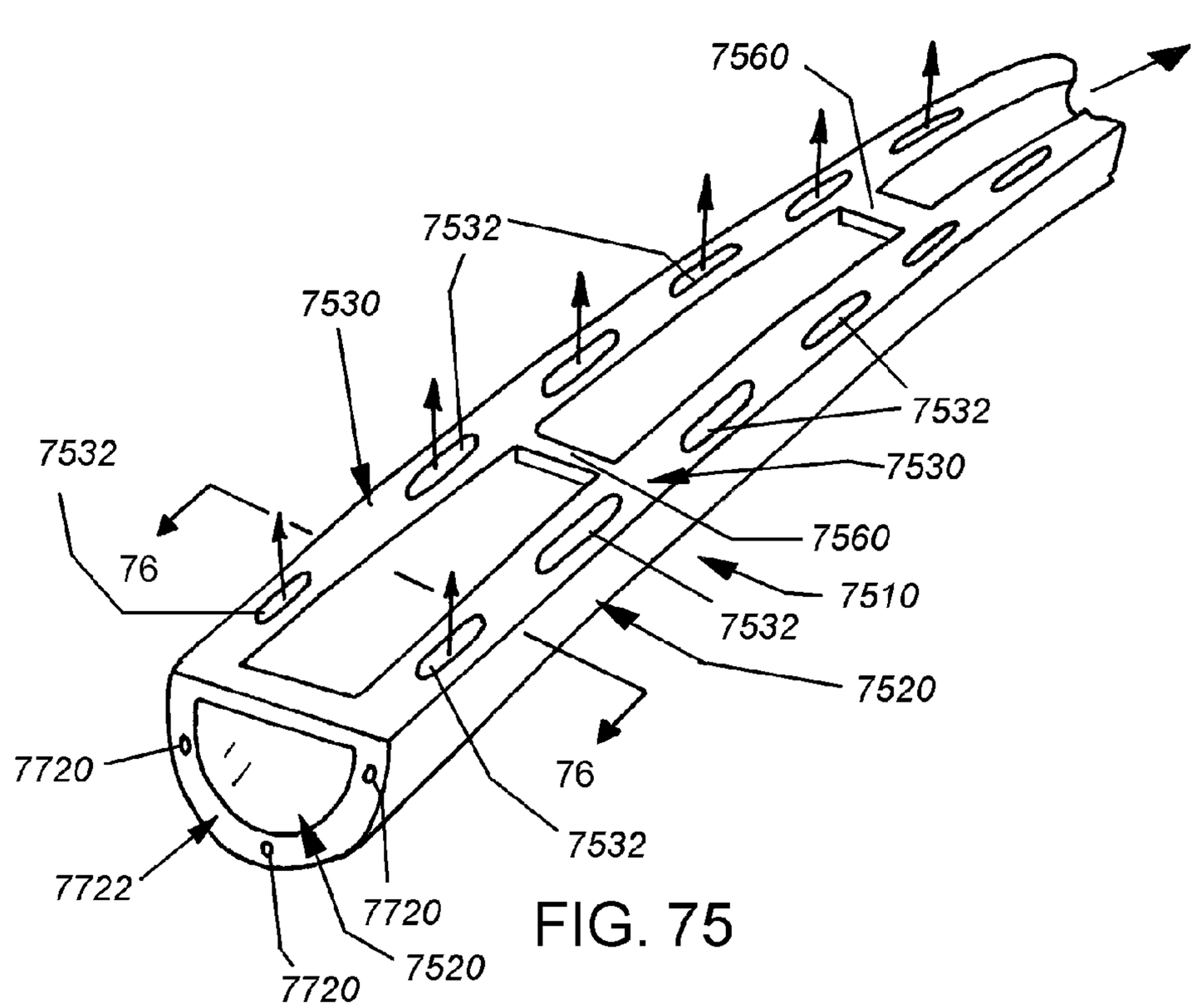
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FIG. 75

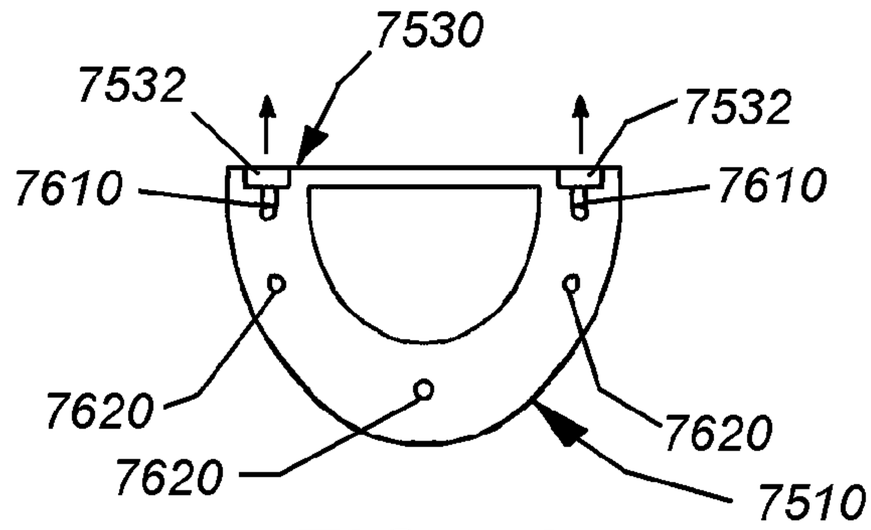
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FIG. 76

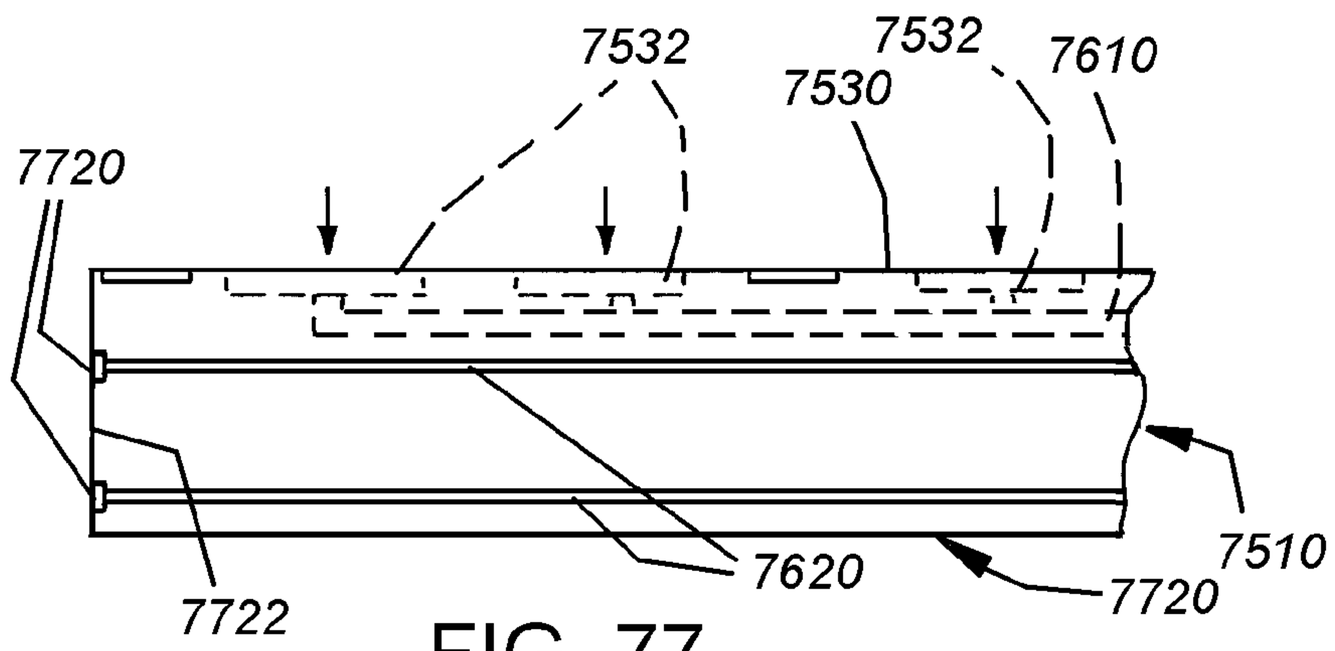
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FIG. 77

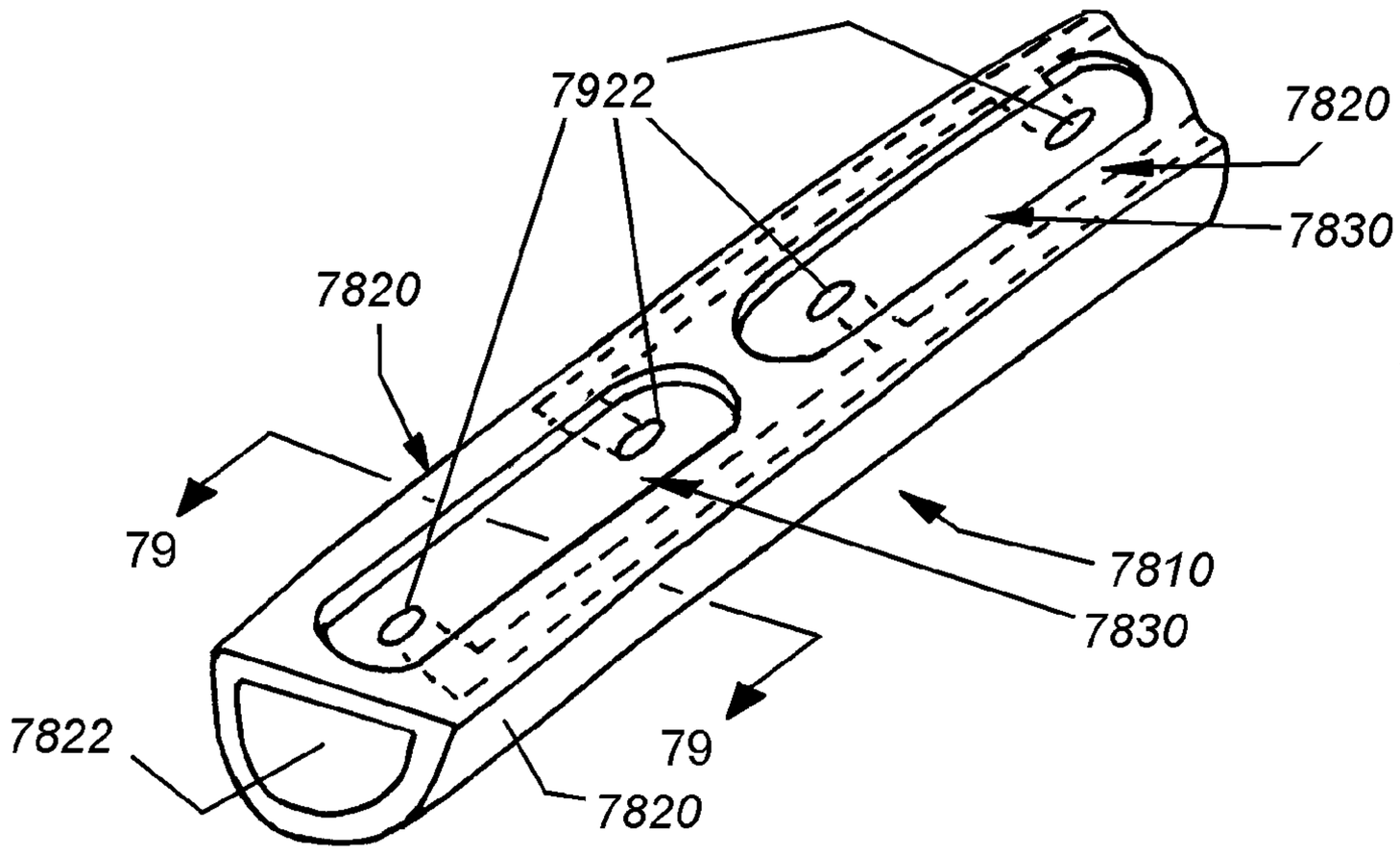

FIG. 78

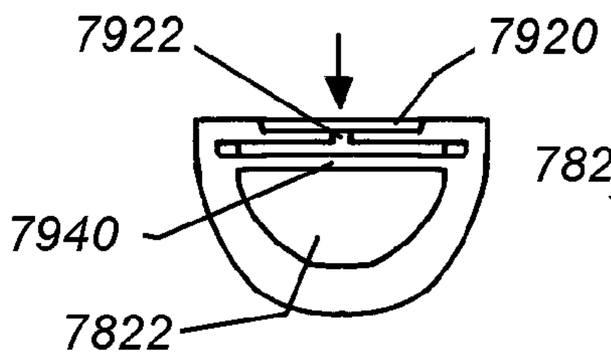

FIG. 79

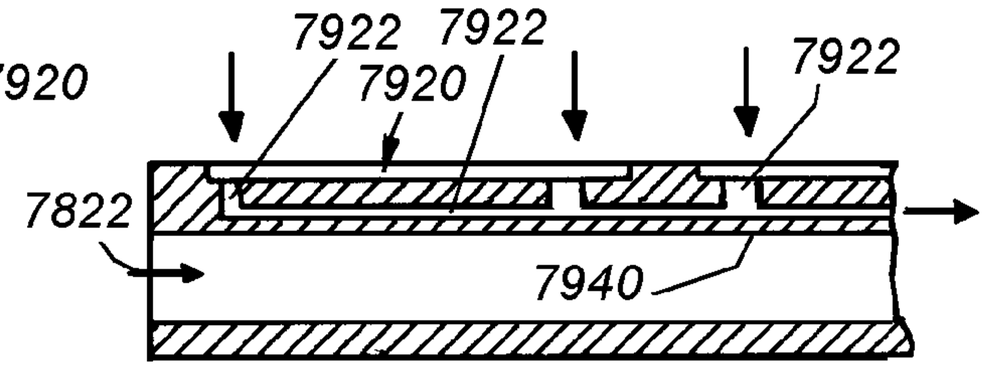

FIG. 80

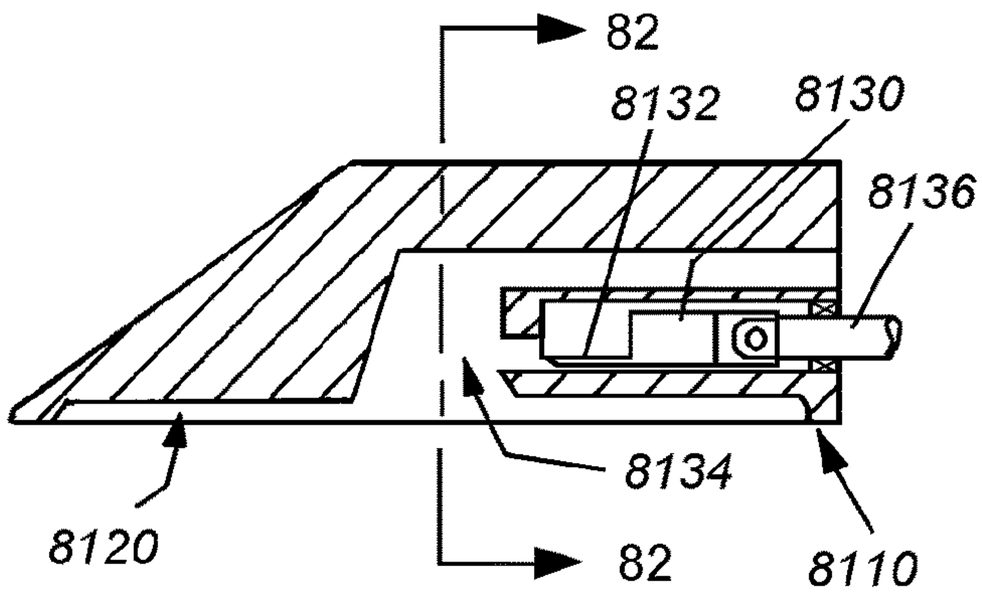

FIG. 81

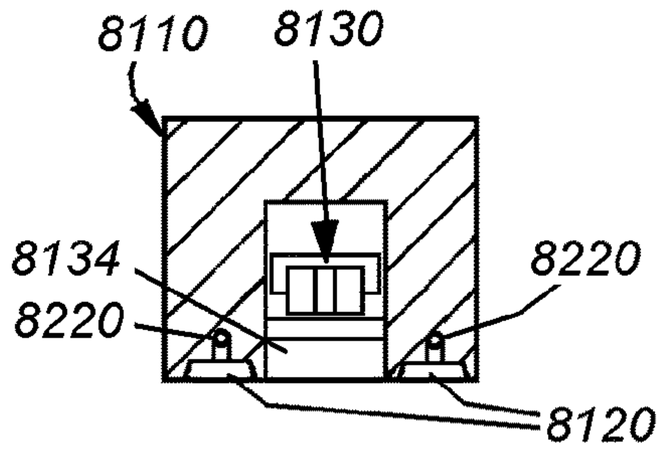

FIG. 82

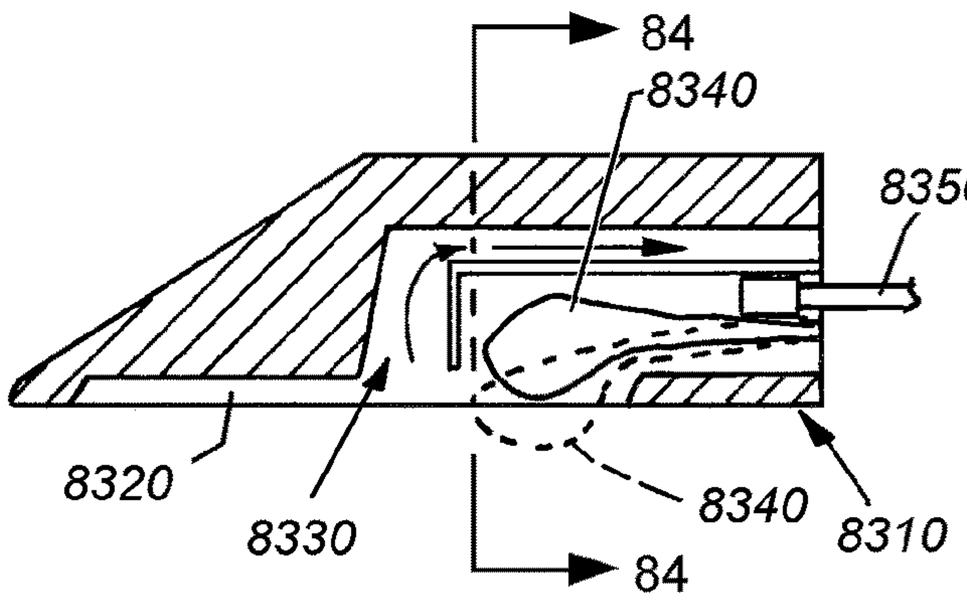

FIG. 83

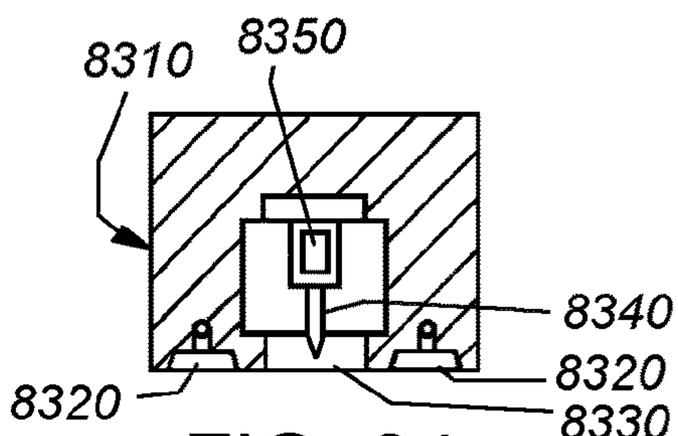

FIG. 84

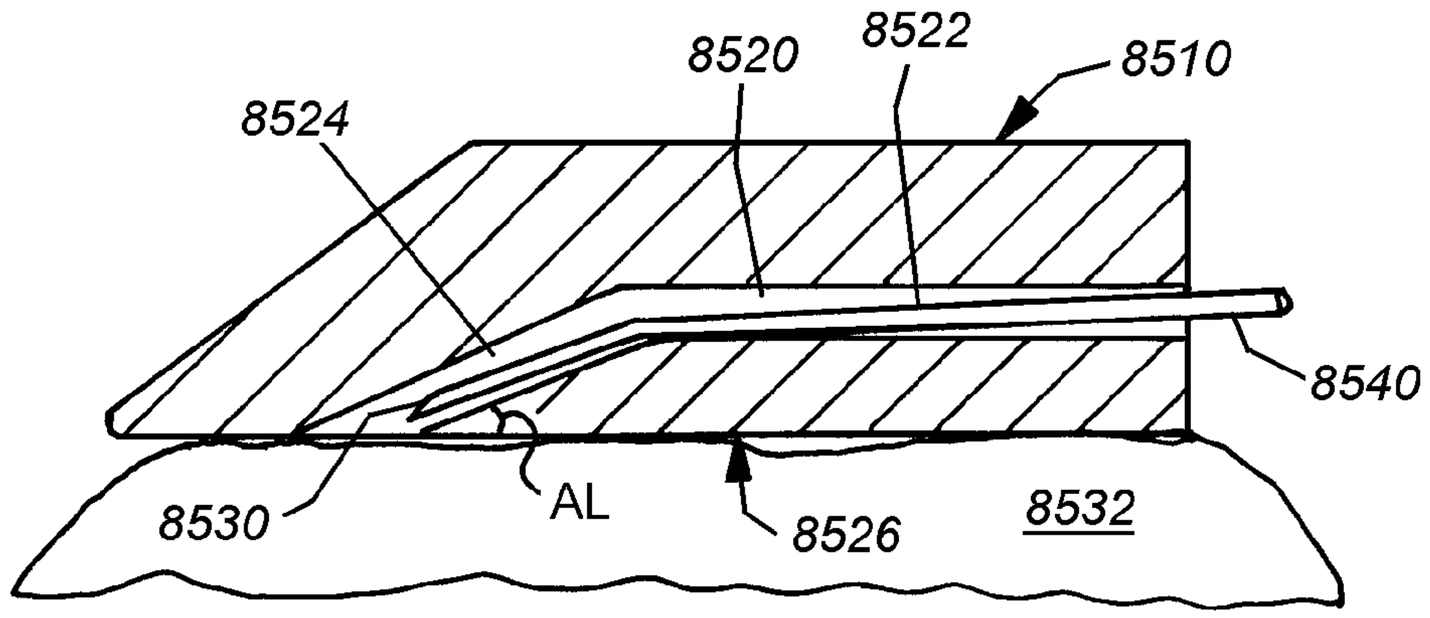
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FIG. 85

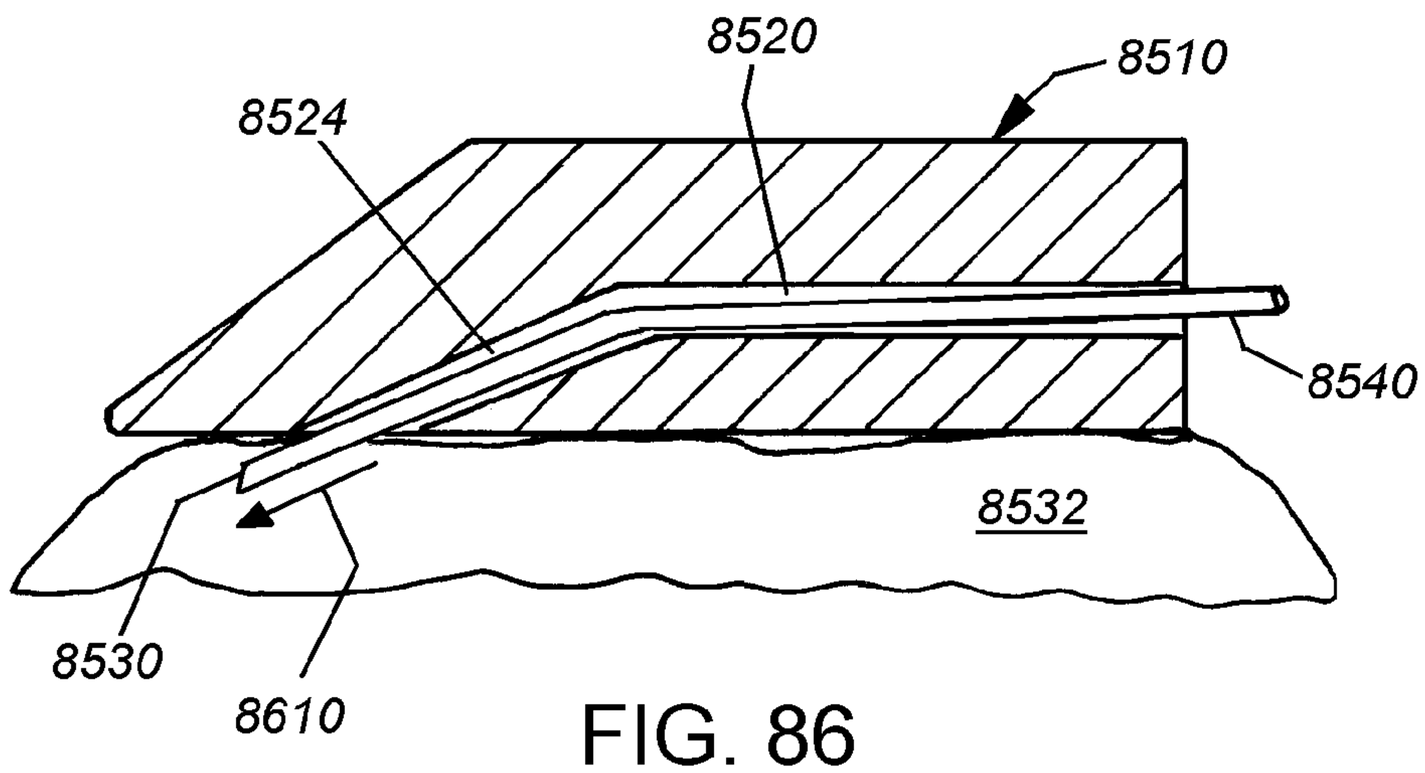
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FIG. 86

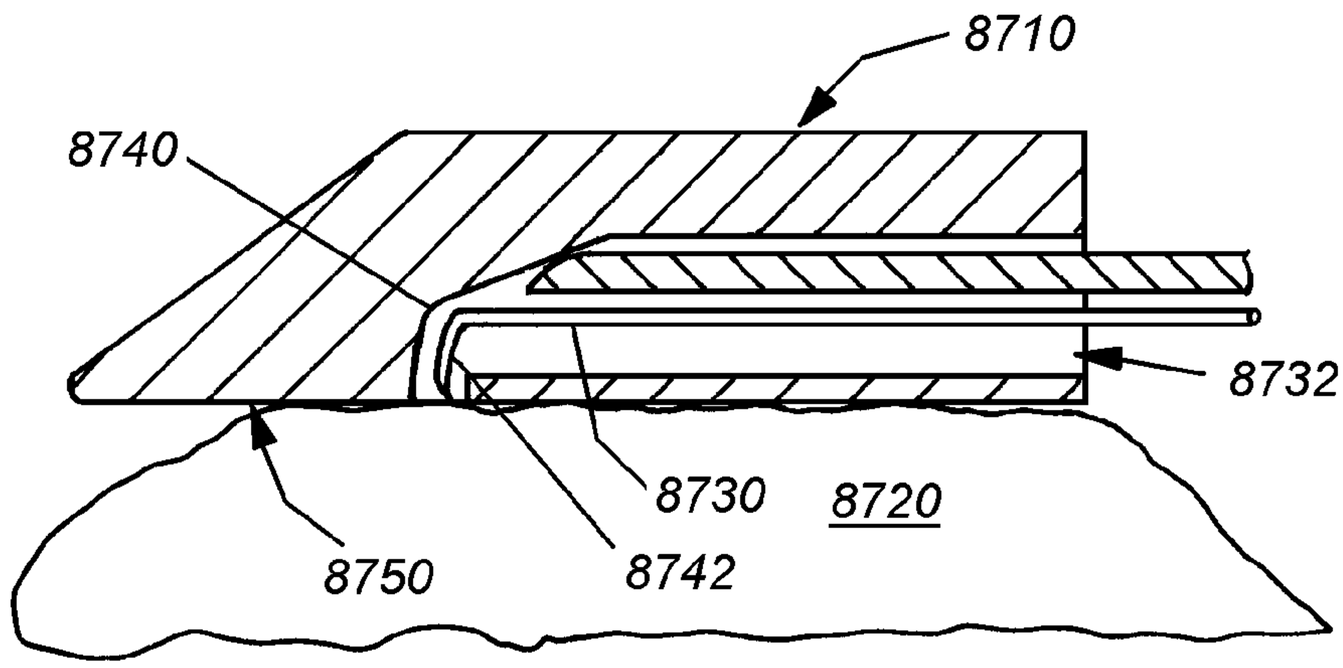
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FIG. 87

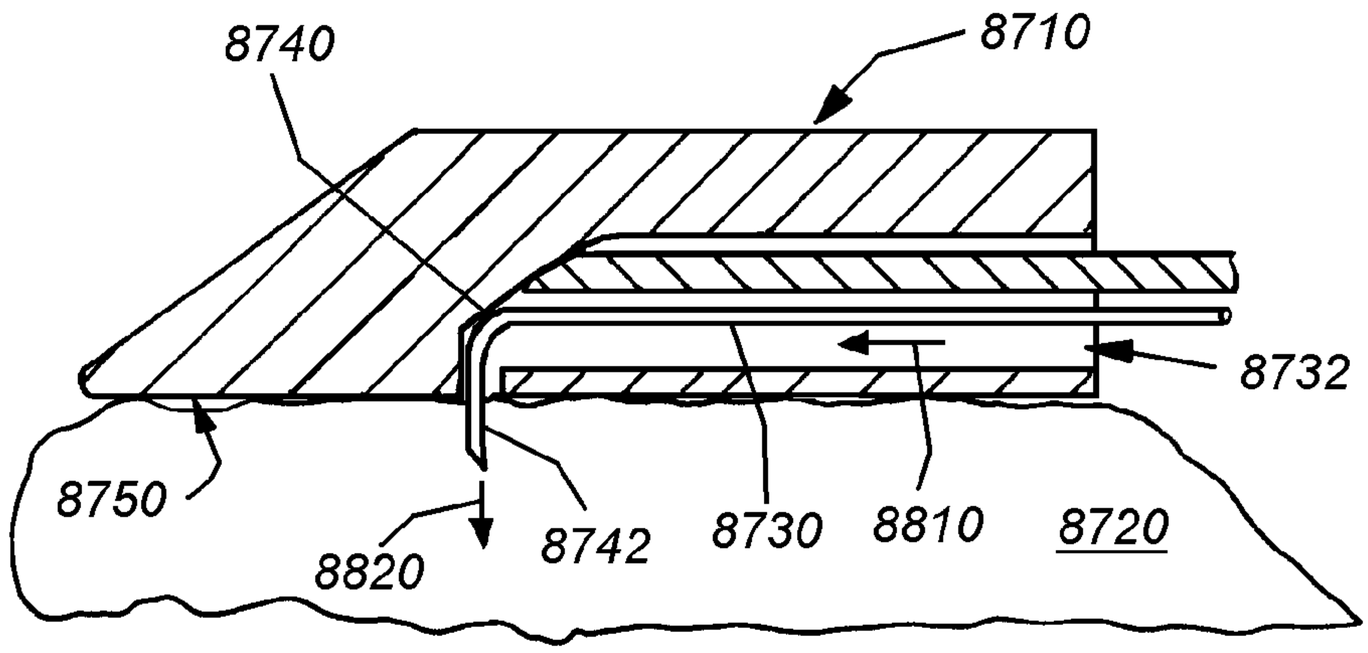
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FIG. 88

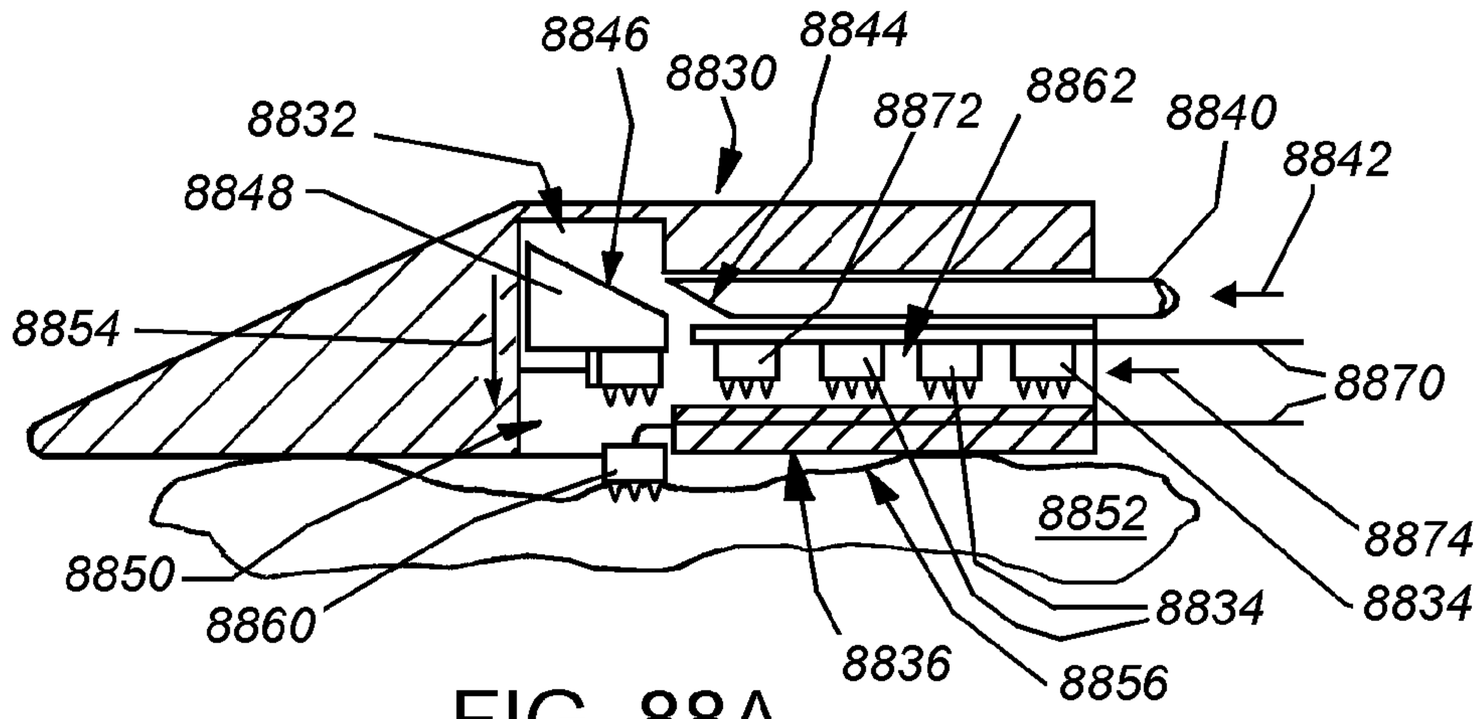

FIG. 88A

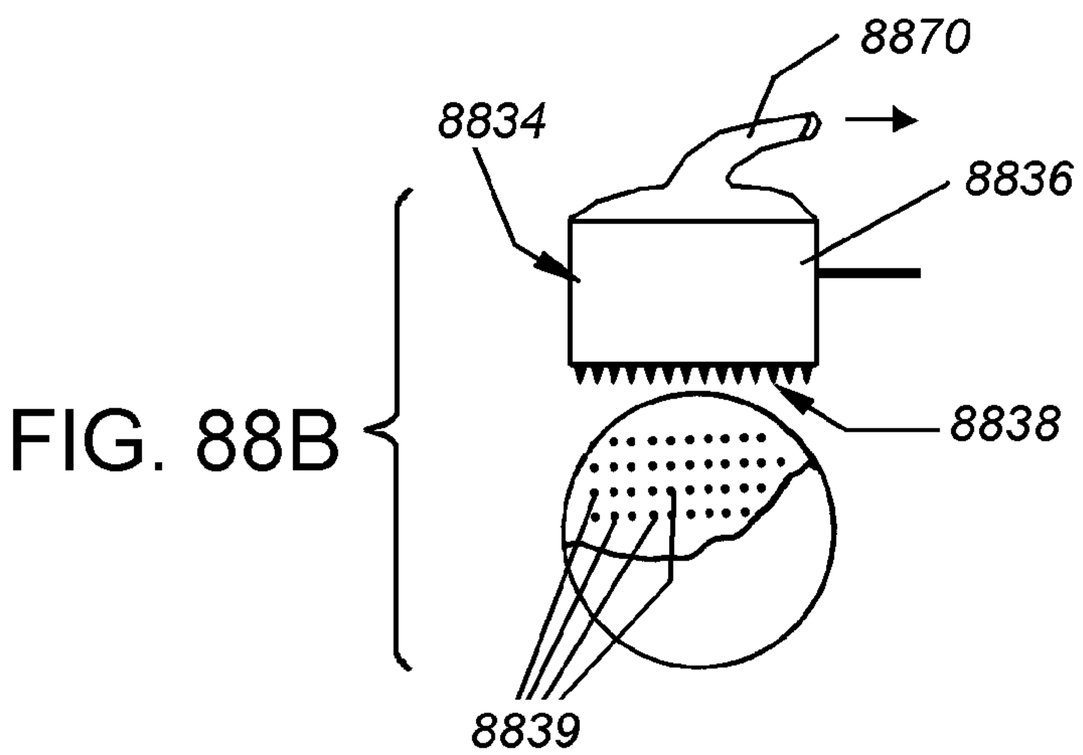

FIG. 88B

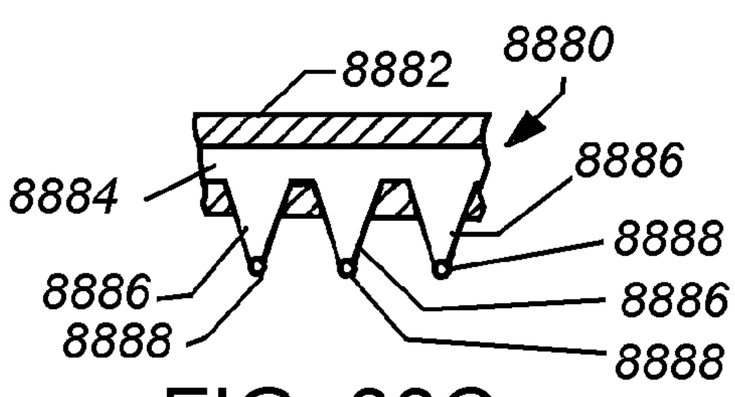

FIG. 88C

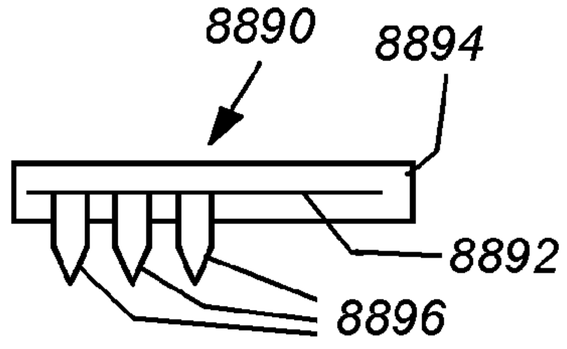

FIG. 88D

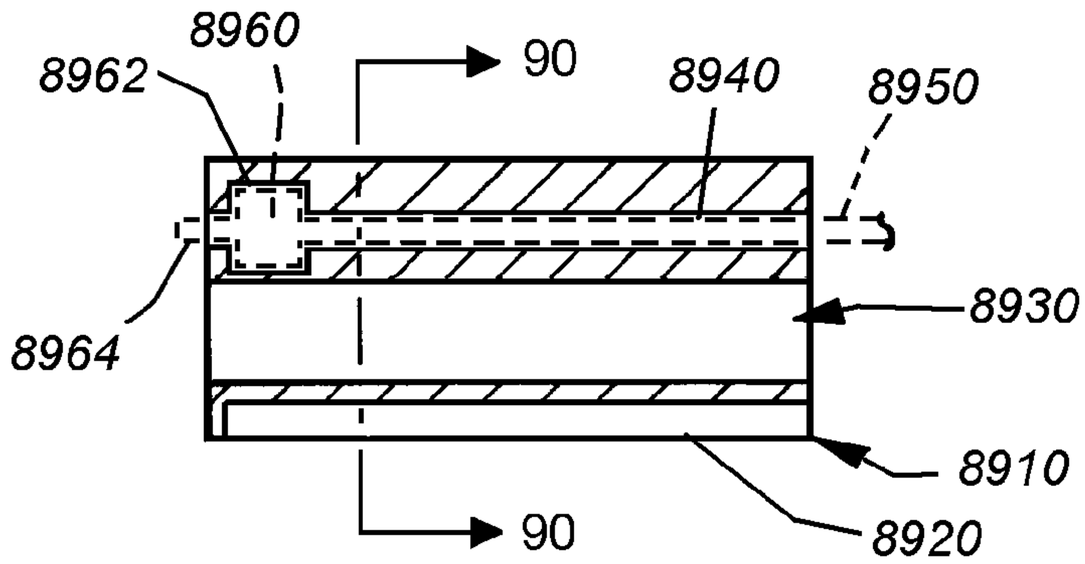

FIG. 89

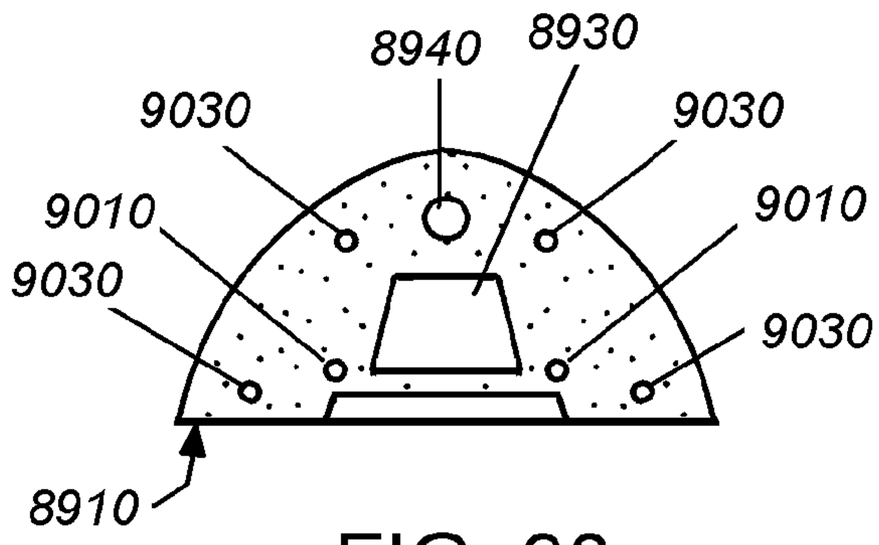

FIG. 90

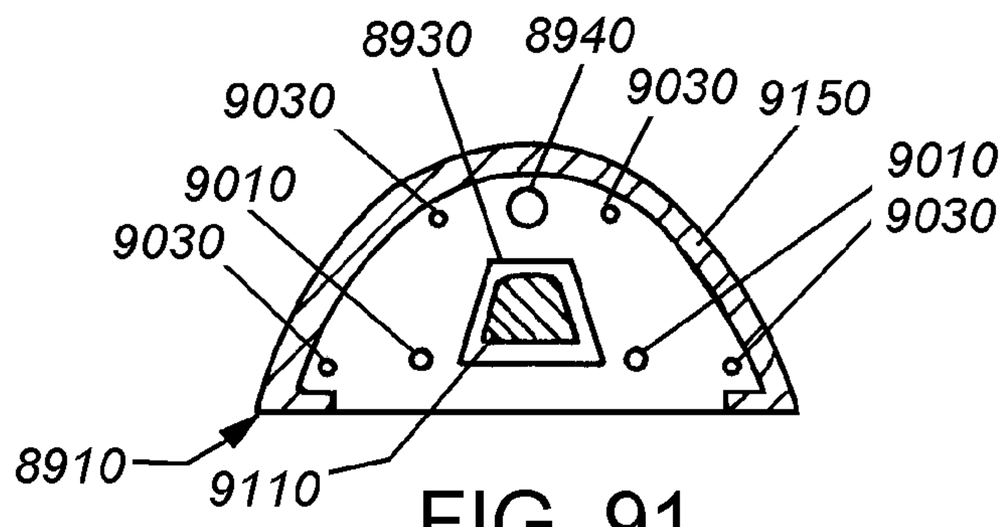

FIG. 91

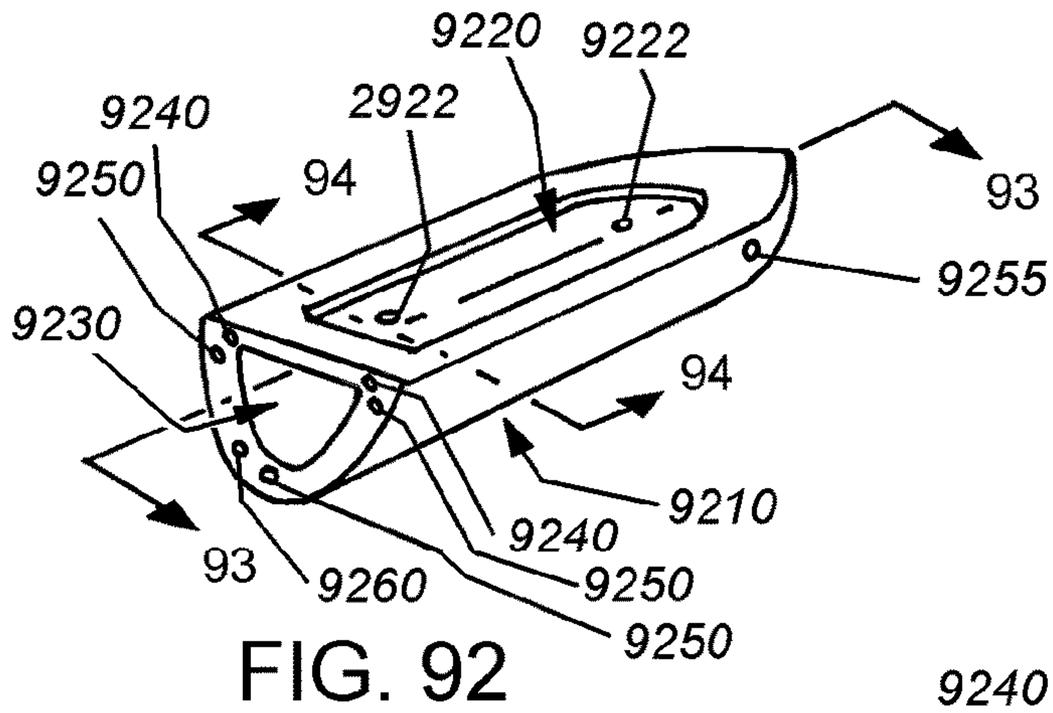

FIG. 92

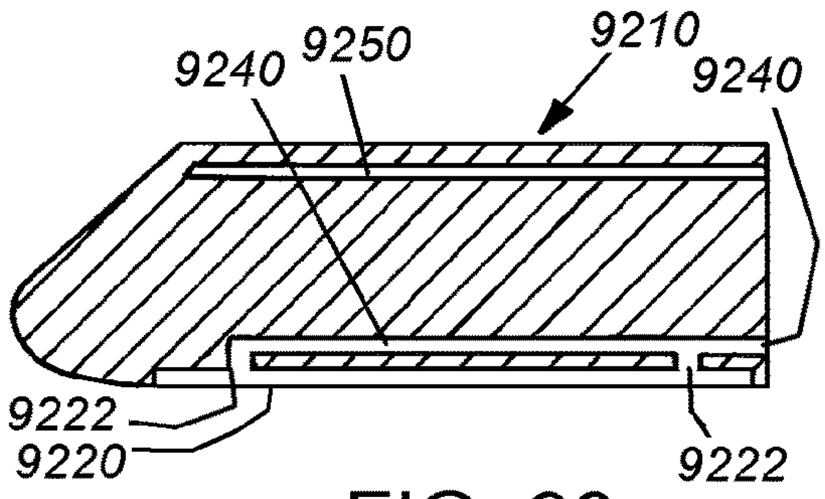

FIG. 93

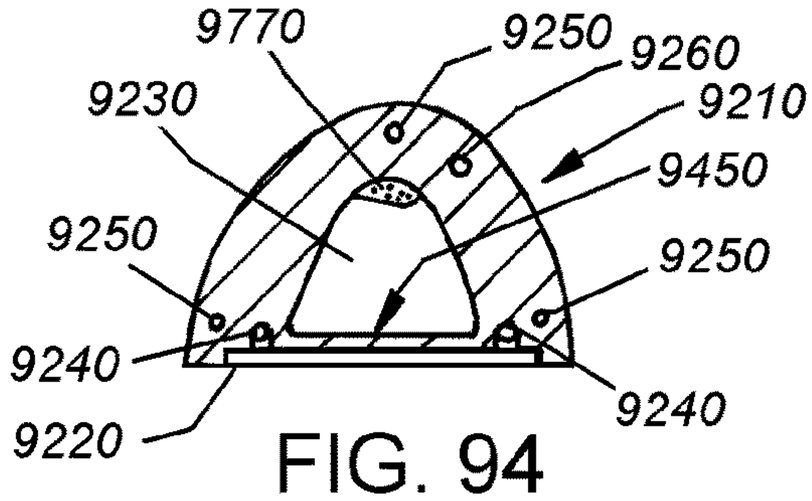

FIG. 94

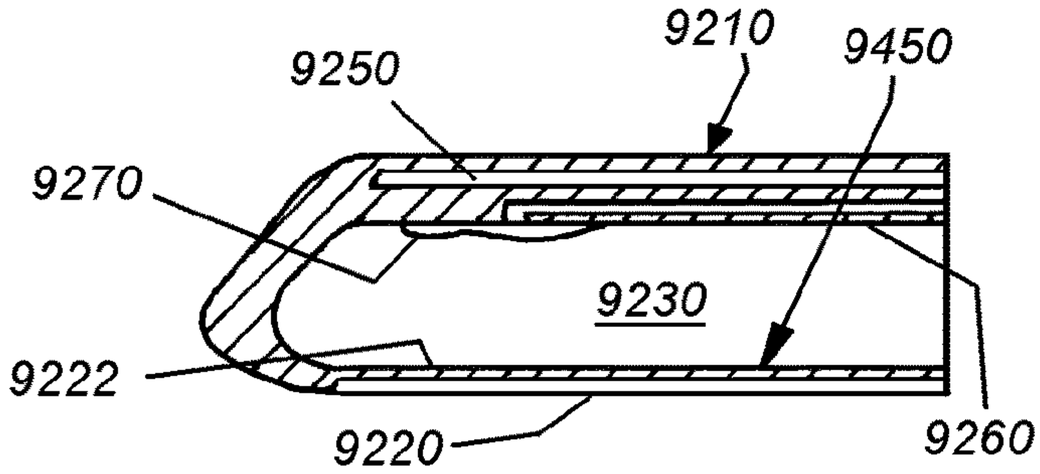

FIG. 95

SYSTEM AND METHOD FOR ADVANCING, ORIENTING, AND IMMOBILIZING ON INTERNAL BODY TISSUE A CATHETER OR OTHER THERAPEUTIC DEVICE

This application is a continuation of U.S. Nonprovisional application Ser. No. 11/694,002, filed Mar. 30, 2007, now U.S. Pat. No. 8,535,304, which claims the benefit of U.S. Provisional Application Ser. No. 60/744,016, filed Mar. 31, 2006, entitled INSTRUMENT TRANSPORTATION AND POSITIONING CATHETER, and U.S. Provisional Application Ser. No. 60/868,951, filed Dec. 7, 2006, entitled ABLATION GUIDANCE SYSTEM FOR MINIMALLY INVASIVE ATRIAL FIBRILLATION SURGERY, the entire disclosure of each application being herein incorporated by reference.

FIELD OF THE INVENTION

This invention relates to systems and methods for performing minimally invasive surgery and more particularly to systems and methods for manipulating therapeutic or diagnostic devices relative to organs and other tissues within a human body cavity.

BACKGROUND OF THE INVENTION

Minimally invasive surgery is becoming the preferred technique for accessing internal organs and systems in an ever increasing number of procedures. Its advantages are manifold. For example, recovery times are greatly decreased due to smaller incisions and less damage to internal structures while gaining access to the procedure site. Also, the risk of post-operative infection is somewhat reduced as the internal tissues are less exposed to non-sterile environments. In addition, the procedure is often simplified and expedited due to the lack of complex incisions and post-procedure suturing of large incisions.

Typically, in minimally invasive procedures, instruments are inserted into the body through steerable catheters that are initially inserted and brought adjacent to the affected organ or other procedure site. However, standard catheters do not stabilize the instrument in place while it is being used by the surgeon. Similarly, standard catheters can only be coarsely steered and are not generally capable of following a serpentine path.

Some specialized mechanisms for stabilizing particular instruments have been devised for procedures that require a close and immobile relationship between the instrument and the tissue being operated upon. For example, Bertolero et al., U.S. Pat. No. 6,849,075 teaches a cardiac ablation device that employs a plurality vacuum orifices to hold an ablation electrode in position on the heart. However, this reference does not provide a mechanism to move the electrode along a serpentine path on the heart or other organ, as may be required in certain procedures, most notably cardiac ablation, as described below. Likewise, there is no mechanism in Bertolero to bring, for example, a microwave ablation catheter into selective contact with heart tissue, as may be required for effective ablation.

An alternate approach suggested for transporting and positioning minimally invasive surgical instruments inside the body is taught by Riviere, et al. in Published U.S. patent application Ser. No. 10/982,670, using a walking robot. The robot comprises two pedestals connected by a spring. The distal pedestal includes a tool, typically a scope for viewing the affected area. The foot of each pedestal has vacuum orifices, with a separate vacuum line running to each pedestal. A pair of pull wires is connected to each pedestal, allowing control of the relative position between the distal pedestal and the proximal pedestal. By properly sequencing the application of vacuum and the tension on the pull wires, a surgeon can cause the robot to "inchworm" across the surface of an organ. Surgical instruments are attached to the front of the distal pedestal.

The Riviere robot employs a large vacuum region that interfaces best with flat organ tissue that is reasonably resilient. Under certain conditions its hold down could become dislodged or allow lateral slippage of the corresponding tool—particularly where the tissue surface is non-flat or roughened. To remedy such slippage, the vacuum applied to each pedestal may be increased. However, under other conditions tissue could be damaged by too intense local vacuum.

Moreover, these and other available devices lack the ability to perform more complex procedures, such as drug delivery, dissection and biopsy. Accordingly, it is highly desirable to provide improved mechanisms and devices for minimally invasive surgical procedures that afford improved function as well as superior mobility, immobilization once positioned, and control of an ablation device or other attached tool.

SUMMARY OF THE INVENTION

This invention overcomes the disadvantages of the prior art by providing a system and method that allows a therapeutic device, such as an atrial fibrillation microwave ablation catheter or ablation tip to be guided to a remote location within a body cavity and then accurately immobilized on the tissue, including that of a moving organ, such as the heart. In various embodiments, the system and method also enables accurate movement and steering along the tissue, while in engagement therewith. Such movement and engagement entails the use of vacuum suction, compression balloon, or microneedle structures on at least two interconnected and articulated immobilizers that selectively engage to and release from the tissue to allow an undulating, step-by-step crawling/walking motion (termed a "traversing" motion herein) across the organ as the therapeutic catheter/tool tip applies treatment (AGE devices). In further embodiments that lack a movement capability (AID devices), the immobilizers allow a predetermined position for the introduced device to be maintained against the tissue while a treatment is applied to the location adjacent thereto. In the exemplary AGE devices, variety of steering mechanisms and mechanisms for exposing and anchoring a catheter against the underlying tissue can be employed. In the exemplary AGE devices, a variety of articulation and steering mechanisms, including those based upon pneumatic/hydraulic bellows, lead screws and electromagnetic actuators can be employed.

In certain embodiments of an AGE or AID, the base includes one or more vacuum structures constructed with an accordion-like or bellows like shape so as to conform to curved surfaces.

In other embodiments of an AGE or AID steering can occur based on a plurality of wires disposed about the perimeter and anchored at an appropriate location on the structure of the device. The wires are selectively tensioned or relaxed to effect steering. A control system joystick or other actuation structure causes tensioning and slacking of the wires.

In other embodiments, generally related to the AGE steering and actuation for (traversing) movement between the proximal immobilizer and the distal immobilizer occurs based upon selective movement of individual bellows disposed between the immobilizers, about the perimeters thereof.

In other embodiments of an AGE, actuation between immobilizers is effected using a flexible or rigid helical drive that is rotated by a shaft operatively connected through the device's proximal cannula with a control system. Where the helical drive is rigid, a universal joint or other flexible, rotating joint can be provided at a location between the immobilizers (at the proximal immobilizer, distal immobilizer, or between the immobilizers). In the above helical drive implementations, steering wires extend from the proximal immobilizer to anchors in the distal immobilizer. In another helical or linear actuation drive define a rigid structure and steering is effected by a pivoting suction cup mounted in the base of the proximal immobilizer, with which the entire AGE pivots in response to steering wires anchored in the proximal immobilizer.

In various embodiments of an AID or AGE, a balloon or bladder is located within a lumen that carries the catheter. This balloon is connected with a pressure/vacuum source. When pressurized, the balloon inflates, thereby frictionally locking the catheter in place against axial pullout and biasing the catheter into a bottom most position with respect to the underlying tissue. In other embodiments, such a lock can be mechanical, such as a sliding contact surface that selectively moves into engagement with the catheter when slid or actuated.

A variety of bellows like structures can be disposed between steerable sections of an AGE or AID. These structures can be actuated by pressure or can be non-actuatable, flexible covers with the actuation mechanism (in the case of AGEs) being another mechanism. Other actuation or actuation/steering mechanisms, with or without an outer bellows covering, include repelling, individually energized arrays of electromagnets, arrays of smaller-diameter pressurized bellows, flexible or pivotal, overlapping piston and cylinder sleeves and push-pull rods actuated by a remote user.

In an alternate embodiment one or more immobilizers can include a plurality of tissue-engaging microneedles that are deployable from locations on the immobilizer base/bottom via pressurized guideways. The needles can be installed in a single elongated base or in a plurality of side-by-side smaller bases so that individual sets of needles can extend different distances to better conform to a curved tissue surface.

Another embodiment of a hold-down mechanism for an AGE or AID comprises one or more inflatable, top-mounted balloons or bladders that are adapted to engage an opposing organ or tissue surface to retain the AGE against the underlying tissue.

An AID can also include a sliding base that moves proximally relative to fixed AID side bases that allows the enclosed catheter to be directly exposed to the tissue. The sliding base can include a steering wire anchored therein. In this arrangement, the hold down mechanism (vacuum ports, microneedles, etc) are located along the side edges of the AID's fixed base section. The AID can also include an exposed mid section base with thin reinforcing ribs at predetermined locations along its length to allow the catheter to be substantially in direct exposure to the underlying tissue. In such an arrangement hold-down vacuum ports or another hold-down mechanism are disposed along the side edges. An AGE can also include a partially exposed mid section with hold-down mechanisms, such as vacuum chambers, on the sides of the exposed mid section. This exposed mid-section allows the catheter to be at least partially, directly exposed to the underlying tissue.

In another embodiment of an AID, the catheter is contained within a series of incrementally spaced horseshoe-shaped hold-down segments that are interconnected by a vacuum lumen that communicate through vacuum ports in the base of each segment.

In other embodiments, the distal (or proximal) end of an AGE can include a deployable therapeutic or surgical tool. In exemplary embodiments, a pneumatic, electromagnetic or mechanical actuator allows a blade or other tool contained within the immobilizer to extend into contact with tissue. In the case of a biopsy tool, tissue can be drawn into a vacuum chamber within the base of the immobilizer for it to be acted upon by a horizontally disposed biopsy blade. Fluid-delivery hypodermic needles can also be deployed either at and acute angle or substantially normal to the underlying tissue by driving the (flexible) needles distally down an appropriately shaped guide lumen into the tissue below.

Certain features of various embodiments described above can be combined variously with others described above to achieve further illustrative embodiments of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention description below refers to the accompanying drawings, of which:

FIG. **1** is an illustration of the initial rubber catheter application step in an exemplary Saltman EndoMAze Procedure (SEMAP) for ablation of cardiac tissue in the treatment of atrial fibrillation according to the prior art;

FIG. **2** is an illustration of an ablation catheter insertion step in connection with the SEMAP of FIG. **1**, according to the prior art;

FIG. **3** is a top rear view of the subject heart undergoing a box lesion ablation step in connection with the SEMAP of FIG. **1**, according to the prior art;

FIG. **4** is an oblique rear side view of the subject heart showing the box lesion ablation step of FIG. **3**, according to the prior art;

FIG. **4** is a perspective view of an ablation guidance enhancer (AGE) for use with an ablation or other therapeutic catheter or device in accordance with a generalized illustrative embodiment of this invention;

FIG. **6** is a perspective view of the AGE of FIG. **5** in engagement with a subject heart;

FIG. **7** is a perspective view of an ablation immobilizer device (AID) for use with an ablation or other therapeutic catheter or device in accordance with a generalized illustrative embodiment of this invention;

FIG. **8** is a cross section of the AID taken along line **8**-**8** of FIG. **7**;

FIG. **9** is a perspective view of the AID of FIG. **8** in engagement with a subject heart;

FIG. **10** is a an illustration of an insertion step for an exemplary AGE (or AID) through the skin and into a subject's thoracic cavity;

FIG. **11** is an illustration of the attachment of the AGE to the subject heart;

FIG. **12** is an illustration of the movement of the AGE along the heart in accordance with an illustrative embodiment;

FIG. **13** is an illustration of the entry of the AGE to the back of the subject heart;

FIG. **14** is an illustration of the first turn of the AGE around the pulmonary veins of the subject heart;

FIG. **15** is an illustration of the use of multiple AGEs (or AIDs) to engage the subject heart;

FIG. **16** is a perspective view of a movable floor for exposing a portion of a catheter enclosed within the central lumen of an AGE or AID according to an embodiment of this invention;

FIG. **17** is a perspective view of an inflatable bladder for displacing, toward underlying tissue, a portion of a catheter enclosed and/or maintaining said catheter's position axially within the central lumen of an AGE or AGE according to an embodiment of this invention;

FIG. **18** is a bottom perspective view of an AGE according to an embodiment of this invention;

FIG. **19** is an exposed cutaway perspective view of the AGE of FIG. **18**;

FIG. **20**A is a side cross section of a distal immobilizer of an AGE including an inflatable luminal catheter-holding mechanism in an undeployed/uninflated orientation according to an embodiment of the invention;

FIG. **20**B is a side cross section of the distal immobilizer of FIG. **20**A showing the catheter-holding mechanism in a deployed/inflated orientation;

FIG. **20**C is a side cross section of an actuatable catheter-holding mechanism in an undeployed/proximally-directed orientation according to an alternate embodiment of the invention;

FIG. **20**D is a side cross section of the distal immobilizer of FIG. **20**C showing the catheter-holding mechanism in a deployed/distally directed orientation;

FIG. **20**E is a partially exposed top view of the distal immobilizer of FIG. **20**C showing the catheter-holding mechanism in a deployed/distally directed orientation;

FIG. **21** is a top perspective view of an AID or AGE having a flexible bellows-like, mid-section joint to assist in actuation and steering functions with respect to a tissue surface;

FIG. **22** a bottom perspective view of the AID of FIG. **21**;

FIG. **23** is a cross section through a mid-section bellows of an AGE or AID adapted for either pneumatic, hydraulic or cable-based steering;

FIG. **24** is a cross section through an immobilizer of the AGE or AID of FIG. **23**;

FIGS. **25-28** are each embodiments of mid-section cross sections of pneumatic or hydraulic multiple-bellows steering mechanisms for an AGE;

FIG. **29** is a perspective view of an AGE having a helix drive movement actuation system according to an embodiment of this invention;

FIG. **30** is a cross section of the AGE taken along line **30-30** of FIG. **29** showing the drive sheath;

FIG. **31** is a perspective view of a helix-drive-actuated AGE having a pivoting suction cup in its proximal immobilizer according to an embodiment of the invention;

FIG. **32** is a cross section of the proximal immobilizer of the AGE taken along line **32-32** of FIG. **31**;

FIG. **33** is a side cross section of proximal immobilizer of the AGE taken along line **33-33** of FIG. **31**;

FIG. **34** is a perspective view of a helix-drive-actuated AGE having a flexible coupling for the drive within the proximal immobilizer according to an embodiment of this invention;

FIG. **35** is a cross section of the AGE taken along line **35-35** of FIG. **34** showing the drive sheath;

FIG. **36** is a partial cross section showing an embodiment of a flexible joint for the helix drive for the AGE of FIG. **34**;

FIG. **37** is a partial cross section showing another embodiment of a flexible joint for the helix drive for the AGE of FIG. **34**;

FIG. **38** is a perspective view of a pneumatic/hydraulic piston-actuated AGE according to an embodiment of the invention;

FIG. **39** is a partial side cross section of the AGE including the piston assembly taken along line **39-39** of FIG. **38**;

FIG. **39**A is a perspective view of an electromagnetically actuated AGE according to an embodiment of the invention;

FIG. **39**B is a more detailed fragmentary cross section of a portion of the electromagnetic actuator for the AGE of FIG. **39**A;

FIG. **40** is a side view of an embodiment of an AGE having an electromagnetic actuator for orienting, advancing and retracting the distal immobilizer with respect to the proximal immobilizer;

FIG. **41** is a cross section of the AGE actuator taken along line **41-41** of FIG. **40**;

FIGS. **42-48** are schematic diagrams detailing various systems that combine actuation and steering between the proximal immobilizer and the distal immobilizer of an AGE, according to various embodiments of the invention;

FIG. **49** is a bottom perspective view of an exemplary AGE showing basic steering and vacuum interconnections with respect to the proximal immobilizer and the distal immobilizer;

FIG. **50** is a bottom perspective view of an exemplary AGE or AID having an enhanced suction pad on each immobilizer for engaging rough or non-flat tissue according to an embodiment of this invention;

FIG. **51** is a partial side view of a suction cup of the AGE or AID of FIG. **50** approaching a non-flat tissue region;

FIG. **52** is a partial side view of the suction cup in engagement with the tissue shown in FIG. **51**;

FIG. **53** is a bottom perspective view of an AGE or AID having a plurality of enhanced suction pads on each immobilizer;

FIG. **54** is another view of the AGE or AID of FIG. **53**, showing the suction ports for each pad;

FIG. **55** is a side cross section of an immobilizer suction pad according to an embodiment of the invention including structures that avoid blockage of vacuum ports by tissue;

FIG. **56** is a bottom view of the immobilizer suction pad of FIG. **55**;

FIG. **57** is a partial side cross section illustrating an appropriate angle for the interior wall of the suction pad of FIG. **55**;

FIG. **58** is a bottom perspective view of an immobilizer for an AGE or AID having an exposed central region;

FIG. **59** is an exposed bottom view of an AGE employing an array of deployable needles and/or microneedles as an immobilization mechanism according to an embodiment of the invention;

FIG. **60** is an exposed side view of the AGE of FIG. **59**,

FIG. **61** is a partial front cross section of the needle deployment mechanism taken along line **61-61** of FIG. **60** showing the needles retracted;

FIG. **62** is the partial side cross section shown in FIG. **61** with the needles deployed;

FIG. **63** is a somewhat schematic top view of an array of individually movable needle sets for use on the bottom of an immobilizer according to an embodiment of the invention;

FIG. **64** is a front cross section of the array taken along line **64-64** of FIG. **63** in engagement with a curving tissue surface;

FIG. **65** is a side view of the array of FIG. **63** in engagement with the curving tissue surface and detailing variable deployment of the needle sets to conform to the curve;

FIG. **66** is a somewhat schematic perspective view of an inflatable bladder on the exterior of the AGE, acting as a hold-down mechanism when bearing against an adjacent tissue surface, according to an embodiment of the invention;

FIG. **67** is a generalized schematic diagram of a guidance system for tan AGE employing a combined bellows actuating and mechanical wire-steering arrangement according to an embodiment of the invention;

FIG. **68** is a block diagram of the primary system components with respect to the guidance system of FIG. **67**;

FIG. **69** is a somewhat schematic side view of a joystick-based steering control employed with respect to the guidance system of FIG. **67**;

FIG. **70** is an exemplary control panel for a Human-Machine Interface (HMI) used in conjunction with the guidance system of FIG. **67**;

FIG. **71** is a more detailed schematic view of a pneumatic or hydraulic actuator control for use with the guidance system of FIG. **67**;

FIG. **72** is a perspective cross section of an immobilizer section of an AGE or AID including a movable floor that allows the inner lumen to become exposed;

FIG. **73** is a top perspective view of an AID according to an alternate embodiment, featuring independent immobilization segments disposed along an exposed catheter;

FIG. **74** is a bottom perspective view an exemplary immobilization segment of the AID of FIG. **73**;

FIG. **75** is a bottom perspective view of an AID according to an alternate embodiment, featuring lateral vacuum ports along its bottom surface;

FIG. **76** is a front cross section of the AID taken along line **76-76** of FIG. **75**;

FIG. **77** is a partially exposed side cross section of the AID of FIG. **75**;

FIG. **78** is a bottom perspective view of an AID according to an alternate embodiment, featuring central vacuum ports along its bottom surface;

FIG. **79** is a front cross section of the AID taken along line **79-79** of FIG. **78**;

FIG. **80** is a partially exposed side cross section of the AID of FIG. **78**;

FIG. **81** is a side cross section of a distal immobilizer according to an alternate embodiment, featuring a biopsy cutting tool;

FIG. **82** is a front cross section of the distal immobilizer taken along line **82-82** of FIG. **81**;

FIG. **83** is a side cross section of a distal immobilizer according to an alternate embodiment, featuring a dissection tool;

FIG. **84** is a front cross section of the distal immobilizer taken along line **84-84** of FIG. **83**;

FIG. **85** is a side cross section of a distal immobilizer according to an alternate embodiment, featuring an acute-angled-entry deployable fluid-delivery hypodermic needle in a retracted position;

FIG. **86** is a side cross section of the distal immobilizer of FIG. **85**, showing the needle in a deployed position, engaging adjacent tissue;

FIG. **87** is a side cross section of a distal immobilizer according to an alternate embodiment, featuring an perpendicularly angled-entry deployable fluid-delivery hypodermic needle in a refracted position;

FIG. **88** is a side cross section of the distal immobilizer of FIG. **87**, showing the needle in a deployed position, engaging adjacent tissue;

FIG. **88**A is a side cross section of a distal immobilizer for an AGE that enables the deployment/implantation of microneedle and microspike implants to tissue for interconnection by wires or tubes to a remote system;

FIG. **88**B is a side and partial bottom view of an exemplary microspike or microneedle implant assembly for use with the immobilizer of FIG. **88**A;

FIG. **88**C is a partial cross section of an exemplary fluid-delivery microneedle structure that can be employed in the assembly of FIG. **88**B;

FIG. **88**D is a partial cross section of an exemplary electronic sensor microspike structure that can be employed in the assembly of FIG. **88**B;

FIG. **89** is a side cross section of a proximal immobilizer for use in rotating/helix drive embodiments showing the location of a flexible joint therefor;

FIG. **90** is a front cross section taken through line **90-90** of FIG. **89**;

FIG. **91** is a front cross section taken through the interconnecting bellows between the distal immobilizer and the proximal immobilizer of FIG. **89**, facing the distal end of the proximal immobilizer;

FIG. **92** is a bottom perspective view of an exemplary distal immobilizer according to an alternate embodiment having an inflatable balloon within the inner lumen for locking a catheter in place therein external steering cable tie-down locations and two vacuum ports according to an embodiment of the invention;

FIG. **93** is a side cross section of the distal immobilizer taken along line **93-93** of FIG. **92**;

FIG. **94** is a front cross section of the distal immobilizer taken along line **94-94** of FIG. **92**; and

FIG. **95** is a side cross section of the distal immobilizer in accordance with FIG. **92**.

DETAILED DESCRIPTION

I. SEMAP Technique

The principles of this invention are generally applicable to the field of endocardial ablation. However, as will be described below, the systems and methods described herein can also be applied to procedures using other types of tools, and applied to procedures involving other internal organs and structures in addition to the heart. In general, atrial fibrillation (AF) is a common, but not fully understood disturbance of the heart's rhythm. It affects more than 2.2 million people in the Unites States. It has been determined that altering the electrophysiological state of the heart is useful in eliminating unwanted electrical activity. This activity is viewed to be the primary cause of AF. A well-known procedure for reducing electrical activity is the Cox Maze Procedure (CMP). This surgical procedure involves the invasive entry of the thoracic cavity to expose the heart. The heart is then dissected, and then re-sewn by sutures to disrupt unwanted pathways of electrical propagation. This procedure has been viewed as successful in a large number of cases.

An alternative to the physical dissection of the heart to attain the desired result is to generate scar tissue in a defined line around the affected regions of the heart by either burning or freezing the cardiac tissue that carries nerve connections deemed to be a cause of AF. The most common procedure, often termed "ablation", involves access to the inside of the heart, via for example the femoral vein.

Typically, these procedures employ radiofrequency energy (RF) that is delivered internally to the left atrium in a catheter that is introduced to the heart via the femoral vein. The RF energy, which typically operates in the microwave band, heats or burns the tissue to a predetermined depth, thereby creating a single-point lesion that cuts the nerve pathway within that area of the myocardial wall. The lesions are overlapped one-upon-another until every point along the electrical pathway has been severed. The success rate in this type of surgery has been measured to be between approximately seventy percent and eight-five percent—rendering it a relatively successful outcome. There are, however, certain well-known side affects that may occur with respect to the endocardial ablation procedures as described above. In order to avoid some of these side affects, and simplify the procedure, Dr. Adam P. Saltman, M.D. PhD. has developed and employed the Saltman EndoMAze Procedure (also termed SEMAP). In practice, this procedure employs bilateral simultaneous thorascopy and the Flex 10® microwave energy ablation catheter formerly available commercially from AFX, Inc. of Fremont, Calif., now Boston Scientific Corporation of Natick, Mass. Briefly, the procedure implicates the encircling of a portion of the heart's exterior (between the pericardium and epicardium) in the region of the four pulmonary veins by the ablation catheter. The encircled area is then heated as appropriate to form the necessary scaring so as to sever the electrical impulses (propagated by cellular conduction) that are believed to be the source of AF.

Referring to FIG. **1**, the SEMAP procedure is initiated by introducing to the thoracic cavity, and then wrapping two rubber guide catheters **102** and **104** around the four pulmonary veins **106**, **108**, **110** and **112** of the subject heart **120**. The catheters can be introduced to the region via minimally invasive techniques, which will be described further below. The two distal ends **122** and **124** of the guide catheters **102** and **104**, respectively, are free until they are tied together to provide the terminal end of the chain around the heart. As shown in FIG. **2**, a microwave catheter **200** (the Flex 10® in this example) is now introduced into the proximal end of one of the elastomeric/rubber guide catheters **102**. In one example another (or the same) microwave catheter may also be introduced into the proximal end/opening of the opposing guide catheter **104**. In alternate embodiments, a loop around the heart using a singe-guide catheter can be provided.

Each introduced microware ablation catheter **200** comprises a series of emitting segments that are joined by adjacent electrical connections. The emitting segments and electrical connections are collectively energized by a power source located external to the patient's body cavity. The application of energy is carefully controlled and monitored to produce the desired level and duration of ablation heat to the pericardium.

As shown in FIG. **3**, the segments lay against the heart in the region of the four pulmonary veins **106**, **108**, **110** and **112**. As further viewed in FIG. **4**, the ablation catheter(s) **200**, which in this embodiment wraps fully around the pulmonary veins, starts at segment **1** as shown with respect to the guide catheter **104** and extends fully around the heart to exit at the opposing guide catheter **102**.

The ablation catheters, once properly placed, are energized using known power application and duration to attain the desired result without excessive burning into the cardiac tissue.

The above-described SEMAP technique still requires substantial effort to affix the guide catheters at the appropriate locations with respect to the heart. In addition there is no particular mechanism to ensure a closely conforming relationship between the pericardial surface and the catheters and the inherent beating of the heart renders the placement and maintaining of the catheters at the appropriate location somewhat challenging.

II. Overview of Inventive Catheters and Introduction to Thoracic Cavity

FIG. **5** details a basic overview of an ablation guidance enhancer (AGE) **500** in accordance with an overall embodiment of this invention. In this embodiment, the AGE **500** acts as a moving system that is capable of contacting coronary tissue (or other internal bodily tissue) along the pericardium, maintaining close, controlled contact with the tissue, while systematically traversing the pericardium to apply the needed ablation energy to sites that are desired in an incremental fashion. That is, in a typical procedure, the AGE moves to a desired location on the heart or other organ, becomes immobilized at that position and the device carried within the AGE, such as an ablation catheter, applies a therapeutic procedure to the underlying tissue.

In this embodiment, the AGE comprises a proximal immobilizer **502** with vacuum hold-down capability or another type of hold-down capability (as described below) along its base **504**. It also comprises a distal immobilizer **506** with similar vacuum or other remobilization capability along its base **508**. Notably, the distal immobilizer **506** of this embodiment, and various other embodiments herein, includes a sloped top surface **510** and similarly inwardly sloped side surfaces **512**. These sloped distal surfaces assist in allowing introduction and internal thoracic movement of the distal immobilizer **506** as will be described below. With reference briefly to FIG. **6**, an illustration of the heart **600** is shown in which the AGE **500** moves along the heart's surface between respective pulmonary vessels **602** and **604** to apply needed ablation energy. The ablation energy, is in particular, provided by a microwave or similar catheter **520** that slides with respect to the proximal immobilizers **502** so as to allow the immobilizers to engaging in the above-described traversing motion across the tissue.

As shown in FIG. **6**, a bellows **620** joins the distal and proximal immobilizers **502** and **506**, thereby protecting the space therebetween from foreign matter. The material as the AGE is one that includes minimal moisture, so as to maximize the transmission of microwave energy without excessive heating. As will be described variously below, the bottom portion of each immobilizer can be enclosed or open, at least in part to allow microwave energy to pass therethrough. To this end, in certain embodiments the bottom portion may be open to the underlying tissue if the material between microwave catheter and target tissue characteristically absorbs and dissipates an unacceptable amount of microwave energy.

The AGE **500** is specifically designed to self-ambulatory, allowing it to be introduced into the body through a small, minimally invasive incision, as will be described below, and then move under its own power, under the manipulation of an operator, to traverse a desired area of contacting tissue. To, thus, summarize an example of the AGE's traversing movement: the distal immobilizer pulls the microwave catheter along, thereby expanding the bellows relative to the proximal immobilizer while the proximal immobilizer remains stationary (held-down) on the tissue. The distal immobilizer then becomes immobile or stationary and the proximal immobilizer is released from the tissue, and moved towards the distal immobilizer, or the bellows contracts, thereby slipping along the microwave catheter. The proxi-

mal immobilizer then reestablishes position in new location and sequence continues if desired.

An alternate arrangement in accordance with this invention is the ablation immobilizer device (AID) as shown in FIG. **8**. The AID **700** includes non-ambulatory segments **702** and **704**. These segments may be steerable but do not perform the traversing function described above. The segments **702**, **704** each contain at base **710** and **712**, respectively, which communicates with an external vacuum source, similarly to the AGE, to apply holding suction to the underlying tissue. In use, the AID **700** is typically manipulated into position using appropriate guide wires, or other like-internal-placement techniques. As shown in cross section in FIG. **8**, the exemplary AID encloses a microwave ablation catheter **810**, similar or identical to the Flex 10 catheter **520** described above. The bottom edges **820** of the AID cross section may contain vacuum ports, as described above, to transmit the necessary hold-down vacuum to the underlying tissue. The central region **830** of the AID cross section is open in this embodiment to allow direct exposure of the microwave catheter's emission surface to the underlying tissue. With a sufficiently long AID, proper steering and placement can allow an entire area of the heart tissue to be ablated at once with the catheter axially fixed within the AID lumen. In other embodiments, the catheter can be moved axially within the lumen of the AID, similar to a train being guided along a track. Hence the AID is anchored on the tissue, and the catheter is moved distally out of the AID's distal end to increase the range of ablation (or another procedure) by treating tissue distally ahead of the AID. To cover a longer area, the AID can be moved and immobilized at another location on the tissue once it has treated a given area.

Note that certain embodiments of the AID contemplate an integral steering mechanism, typically employing a plurality of selectively tensioned wires about the perimeter. However, in a variety of illustrative embodiments, the AID is free of any steering function, acting as a passive, hold-down device. In a non-steerable form of the AID, other minimally invasive instruments are used to position the AID, including, but not limited to, trocars, guide catheters and steerable catheters with lumens through which the AID is passed. The AID basically functions to piggy-back the ablation catheter or other device as appropriate. The AID can also be employed to surround any catheter-like therapy device.

As shown in FIG. **9**, the AID **700** of this example is applied to a subject heart **900** between the pulmonary veins **902** and **904** to achieve a desired ablation in accordance with the principles of the above-described SEMAP technique. That is, the AID is selectively positioned so as to surround the four pulmonary veins and thereby generate scar tissue to block the electrical pathways in this ringed region.

Referring now to FIGS. **10** through **14**, the introduction of an exemplary AGE to the thoracic cavity and subject heart is shown in further detail as part of a minimally invasive surgical treatment to treat AF. As noted above, this procedure is altered appropriately to introduce a non-ambulatory AID, in that an underlying guide catheter must be directed to the affected tissue site, and thereafter located so that the AID can take hold of the tissue on its own. Conversely, the AGE may engage internal organ tissue at any given location thereon, and then subsequently move to (and along) a desired location on the organ.

As now shown if FIG. **10**, a trocar **1010** has been passed through an incision **1012** in the skin **1014** covering the patient's thoracic cavity **1016** so that the distal end **1018** of the trocar is adjacent to the heart **1020**. The AGE **1030** is introduced through the trocar **1010**, and now extends out of the distal end **1018**. The AGE catheter's proximal end **1032**, which typically includes a covering cannula, extends out of the flared proximal end **1034** of the trocar. The proximal cannula (**1032**) can extend from the proximal face of the proximal immobilizer back to a remote control system and appropriate power sources, as described further below.

Typically, the AGE or AID in this and other embodiments described herein defines an external shape capable of fitting within a generally cylindrical outline of approximately 10 to 14 millimeters in diameter so as to fit smoothly through a standard surgical cannula, which is typically approximately 15 millimeters in internal diameter.

The AGE **1030** of this embodiment includes a proximal immobilizer **1040**, a distal immobilizer **1042**, an interconnecting bellows **1044**, and appropriate steering wires **1046** that surround the central axis **1048** of the AGE **1030**. Briefly, in operation, a vacuum is applied to each immobilizer **1040** and **1042** to cause the immobilizers to selectively engage the underlying (heart) tissue. This engagement is shown generally in FIG. **11**. As detailed therein, the distal and proximal immobilizers **1042** and **1040** have now engaged the tissue **1110**. The microwave ablation catheter **1060** is contained within the distal and proximal immobilizers **1042**, **1044**, and extends proximally through the trocar **1010**. The catheter **1060**, which may also be enclosed within the proximal cannula **1032**, is ready to be energized when the distal and proximal ends are positioned at the appropriate site on the heart **1020** for ablation. Thereafter, the AGE **1030** is directed by the practitioner to walk or perform the crawling/traversing motion across the heart surface, sequentially immobilizing itself by activating the vacuum in both immobilizers and then energizing the catheter for the prescribed time period so as to generate a scar tissue through selective heating. Progress of the catheter as it crawls along the surface can be tracked in a variety of ways. In general, the catheter and/or the AGE (or AID in other embodiments) can include radio opaque inserts and/or fillers that enable it to be easily tracked using scanning techniques such as fluoroscopy. Ultrasound and/or other internal imaging techniques can be employed. In alternate embodiments, a second endoscope can be inserted into the thoracic cavity to visually monitor the moving AGE's progress.

As shown in FIG. **12**, using the proximally located control system, the distal immobilizer **1042** of the AGE **1030** is caused to extend outwardly (arrow **1210**) by action of the bellows **1044** or another actuation device, as described below. In operation, the distal immobilizer **1042** extends outwardly after the local vacuum to its base has been deactivated. Meanwhile, the vacuum on the proximal end **1040** is maintained. Subsequently, the proximal immobilizer **1040** is brought forward along the path of travel by releasing its vacuum and contracting the bellows **1040**. At this time, the distal immobilizer's vacuum is maintained so that it maintains its hold against the tissue **1040**. This traversing technique of crawling around the heart's surface allows each length of targeted tissue along the pathway to be incrementally radiated with microwaves and, thereby, ablated as appropriate.

To access more-remote portions of the heart, a trocar **1310** can be inserted through a backside incision **1320** as shown in FIG. **13**. The AGE **1030** moves along the rear of the heart **1020** as shown to apply ablation energy to rear portions of the heart **1020**, behind the pulmonary veins **1330**, **1332**, **1334** and **1336**. With reference now to FIG. **14**, the walking action of the AGE **1030** allows it to move around the veins as shown. It should be clear that a variety of introduction

techniques are expressly contemplated herein. These techniques will depend, in part, upon whether an AGE or AID is being employed.

As shown in FIG. **15**, it is contemplated that a larger-diameter trocar **1510** can be used to introduce multiple AGE or AID units **1520**, **1530** and **1540** somewhat simultaneously to the treatment area of the heart **1550**. Each of these devices can be energized in turn, or simultaneously, to achieve the desired ablation of the underlying tissue.

III. Immobilization/Hold-Down Mechanisms

One form of AID that can be implemented in accordance with the embodiment of FIG. **15** (or other embodiments herein) is shown in FIGS. **16** and **17**. The depicted AID **1600** of this embodiment includes an open, inverted-U-shaped top section **1610** having a pair of outwardly extended basis **1620** that provide a somewhat "Omega" outline to the device's cross-section. The interior lumen **1630**, is sized and arranged to accommodate a microwave ablation catheter, or another similarly sized/shaped catheter. To facilitate insertion the catheter's bottom side **1638** remains enclosed. The center of the catheter's bottom **1638** comprises a slidable bottom member **1640** that moves axially (double arrow **1642**) as desired. It is controlled from outside the patient's body by grasping, and withdrawing proximally, a proximal end of the sliding base **1640** (or an interconnected element).

The catheter **1710** is shown inserted through the lumen **1630** in FIG. **17**. The catheter **1710** extends beyond the distal end **1720** of the AID **1600** in this example, but can reside flush with or internal to the AID in alternate arrangements. The base **1640** has been removed to allow the catheter to be exposed relative to the underlying tissue. As described below, a variety of mechanisms can be used to share and steer the device. To facilitate shaping and steering, a series of V-shaped cutouts **1650** are provided along the base **1620**. These cutouts **1650** provide stress-reliefs that enhance the bendability/steerability. In general, the cross section shape of this AID **1600** defines an "omega" shape with an inverted-U-shaped top **1610** and opposing, outwardly extending bases **1620**. The omega cross section is inherently stiffer in the plane parallel to the bases **1620** on the tissue interface surface. Based upon this geometry, the depicted V-shaped **1650** cutouts provide a desired selective reduction in stiffness at their vertices of the, inducing the catheter to bend in the region of the cutouts **1650**.

Note that the sliding central base **1640** rides within a corresponding key slot **1660** formed into each side of the device's interior wall. These key slots **1660** ensure that the base **1640** does not become inadvertently dislodged. As will also be described below, the base **1620**, or another portion of the device **1600** includes a plurality of vacuum ports that are selectively operated to cause the device to become firmly adhered to, and immobilized upon, the underlying tissue when the vacuum is applied.

While discussed further below with respect to additional features according to embodiments of this invention, this embodiment of the AID **1600** includes an inflatable bladder or balloon **1670** near its distal end at the top of the interior lumen **1630**. This feature is also applicable to other AID/AGE embodiments herein. The bladder **1670** communicates with a pressure source that can be routed through a lumen **1672** (shown in phantom) in the top wall of the device proximally to the control system that is external of the patient's body. When uninflated, the balloon allows passage of the catheter **1710** therethrough. When subsequently inflated, as shown in FIG. **17**, the catheter is forced downwardly through the now opened bottom slot, and into closer proximity to the underlying tissue. This arrangement can improve the efficiency of ablation in this embodiment. The length of extension of the bladder **1670** along the longitudinal/axial direction of the AID **1600** is highly variable and depends, in part upon how long a section of catheter **1710** is to be displaced toward the underlying tissue.

Reference is now made to FIGS. **18** and **19**, which show an exemplary AGE **1800**, respectively, in full external bottom view, and also in partial bottom cutaway. The microwave ablation catheter **1810** can be seen clearly passing through the AGE structure. A proximal cannula **1820** is provided ahead of the actual AGE **1800** to encase and guide the catheter **1810** and any surrounding wires, cables, lumens, etc., which are used to control and monitor the AGE. The cannula **1820** can extend fully to the actuation and/or guidance control system, which will be described further below, or the cannula can be truncated as appropriate. In most embodiments, the cannula **1820** extends the full distance proximally to the guidance system.

A set of at least three, circumferentially spaced steering wires **1830** extend through appropriately positioned lumens **1832** in the cannula **1820**, and thereafter into each of the proximal immobilizer **1840** and distal immobilizer **1842**. Typically the steering wires pass slidably through the proximal immobilizer **1840** and are distally anchored in the distal immobilizer **1842**. A flexible bellows **1850** joins the proximal immobilizer **1840** and distal immobilizer **1842**. This bellows can be sealed to the distal face **1844** and the proximal face **1846** of the distal immobilizer so as to allow an applied vacuum to cause the bellows to contract and thereby move immobilizers toward each other, or an applied pressure will move the immobilizers away from each other. This is one more possible mechanism for actuating movement in the AGE, although a plurality of alternate actuation mechanisms are described below. In alternate embodiments, the bellows **1850** is not the actuation mechanism and acts as an outer cover to protect underlying steering and actuation components. In certain non-bellows-actuating embodiments, this outer bellows can be omitted entirely.

The base **1860** and **1862** of each immobilizer **1840** and **1842**, respectively, includes the central cavity or chamber **1864** and **1866**, respectively. Each vacuum cavity **1864**, **1866** comprises a vacuum chamber that is designed to bear against the underlying tissue. In this embodiment, a respective pair of vacuum ports **1866** is provided to each immobilizer's vacuum cavity **1864**, **1866**. Each pair of vacuum ports **1866** is connected to a respective vacuum source lumen that extends proximally to the control system, one of which lumens **1910** is shown, extending through the AGE **1800** to the distal immobilizer **1842**. Each vacuum source lumen extends respectively to each of the immobilizers, thereby allowing each immobilizer's applied vacuum to be individually controlled. This in-part allows the crawling/traversing-type movement described above, as each immobilizer can be individually anchored to the tissue, while the other moves along the tissue.

As discussed above, within the bellows **1850** a variety of "actuation" mechanisms can be provided that allow the proximal immobilizer **1840** to move toward and away from the distal immobilizer **1842**, thereby providing the desired movement across the surface. Likewise, the steering wires **1830** each selectively transmit tension between the proximal and distal immobilizers allowing distal immobilizer to deflect relative to the proximal immobilizer. As it is deflected at an angle, the distal immobilizer can be pushed forward by the actuation function, and thereafter secured to a new location. In this embodiment, each base includes a pair of linearly oriented electrodes **1870** and **1872** that can

measure electrical conductivity, and thereby allow the user to confirm when a given base is in firm contact with an underlying tissue surface (among other readings). Transmission of electrical impulses between the electrodes **1870** indicates that both electrodes are contacting the tissue. In particular, these electrodes **1870** can be used to verify that a therapeutic ablation has been applied by determining if the applied ablation adequately disrupted an electrical test signal transmitted by the control system between the two electrodes along the contacted underlying tissue therebetween. In this embodiment, because the material of the AGE is relatively transparent to microwave energy (a silicone formulation, for example), the microwave energy passes through the AGE and heats the underlying tissue, which is saturated with moisture, and thereby increases in temperature in response to the applied microwave energy. As noted above, various vacuum conduits, electrical wires, and other needed components pass through appropriate lumens along the AGE **1800**, and proximally back through the cannula **1820**.

Various embodiments of the AGE shown herein include a central lumen that is particularly sized and arranged to receive a therapeutic catheter. The lumen can be sized to closely conform to the shape of the catheter, or it can be somewhat oversized, allowing the catheter appropriate play within the device. The catheter shaft can be allowed to slide freely within the AGE or it can be anchored at some location along the AGE and/or proximal cannula. FIGS. **20**A and **20**B detail a mechanism for locking the catheter axially in place with respect to the AGE. This mechanism is structured and functions similarly to that of FIGS. **16-17** above. The mechanism is shown within an exemplary distal immobilizer **2000**, which can include a variety of actuation, steering and immobilization systems in accordance with various teachings of this invention. This mechanism can also be applied to the proximal immobilizer or along the device cannula where appropriate.

As shown in FIG. **20**A, the distal tip **2002** of the immobilizer is angled for improved insertion as discussed above. The tip **2002** in this embodiment, and various other embodiments, encloses the distal end of the immobilizer lumen **2003**, and includes a front wall **2004** that is internally shaped to approximately conform to the distal end **2006** of a catheter **2010**, which is also angled. A catheter with a non-angled tip can be used in alternate implementations.

As shown further in FIG. **20**A, a deflated balloon or bladder **2011** is located on the inner top wall **2012** of the immobilizer lumen **2003**. This balloon **2011**, like others described variously herein can be constructed from any acceptable, pliable and expandable/elastic, thin-walled material. The balloon communicates with a lumen **2014** that interconnects with a pressure and vacuum source at the control system. As shown, a vacuum (proximal arrow **2016**) has been applied through the lumen **2016** to evacuate and deflate the balloon **2011**. This deflation creates an open gap **2018** between the top **2020** of the catheter **2010** and the balloon. This allows the catheter **2010** to move freely within the lumen **2003**.

As shown in FIG. **20**B, a pressure (distal arrow **2022**) is now applied to the lumen **2014** and balloon **2011**. This pressure causes the balloon **2011** to inflate as shown. The inflation causes the balloon to fill the gap **2018** and apply downward pressure to the catheter that forces (arrows **2023**) it against the bottom wall **2024** of the immobilizer **2010**. This engagement, as well as engagement with the balloon generates holding friction that resists axial (along the axis **2026**) pullout of the catheter **2010** from the immobilizer **2000**. This arrangement also advantageously moves the catheter to its bottommost orientation so that the distance from the underlying tissue is minimized and predictable.

As described herein, many functions, such as steering and actuation can be implemented using mechanical push-pull mechanisms, which are either manually or mechanically (using electrical, pneumatic or hydraulic actuators) actuated by the user at the control system-end. FIGS. **20**C-**20**E shows a version of the distal immobilizer **2050** that houses the catheter **2010** similarly to the immobilizer **2000** above. This immobilizer **2050** includes a mechanically actuated, push-pull catheter locking mechanism according to an alternate embodiment of this invention. The top wall **2052** of the immobilizer **2050** defines a gap **2050** that allows some lateral movement in the catheter **2010** with respect to the catheter lumen **2056**.

A sliding base **2058** having an elastomeric contact surface **2060** rides axially along the top wall **2052**. The sliding base **2058** is interconnected with a flexible shaft **2062** that extends proximally back through the proximal immobilizer (proximal components not shown), and back through the cannula to the control system. An appropriate lumen in the proximal immobilizer and cannula can be provided to guide this shaft **2062** and any other push-pull flexible shaft(s) described herein. Within the top side of the base **2058** and/or shaft **2062** is defined a detent **2064**. The detent is adapted to ride over a domed locking projection **2066** formed in the top wall **2052** of the immobilizer lumen **2056**. In a retracted position as shown in FIG. **20**C, the flexible shaft **2062** positions the base **2058** proximally of, and out of engagement with the projection **2066**. In this position, a gap **2070** exists between the top **2012** of the catheter **2010** and the bottom of the contact surface **2060** of the locking mechanism.

When the catheter is appropriately axially positioned within the lumen **2056**, the shaft **2062** is slid distally (arrow **2072**) by the user. Note in FIG. **20**E that the base includes side wings **2080** that are adapted to ride on slots **2082** formed in the immobilizer's top. This sliding action causes the base **2058** to ride over the projection **2066** until the detent **2064** comes in to engagement with the projection **2066** as shown in FIGS. **20**D and **20**E. In this position, the gap **2070** is closed and the elastomeric contact surface **2060** is elastically deformed as it bears pressurably against the top **2012** of the catheter. This provides a frictional hold against the catheter **2010**, and also causes the catheter to bias (arrows **2074**) against the bottom **2076** of the immobilizer **2050**. The pressure is sufficient to resist axial pullout of the catheter relative to the lumen **2056**. This mechanism can alternately be applied to the proximal immobilizer or cannula. To release the holding pressure, the user draws the shaft **2062** distally to move the base **2058** out of engagement with the projection **2066**. This again defines the gap **2070** between the catheter top **2012** and the contact surface **2060**.

It should be clear that a variety of mechanisms can be adapted to lock the catheter with respect to the AGE or AID lumen. These mechanisms can be driven by a variety of motive forces including, but not limited to, manual force, electromagnetics, pneumatics and hydraulics. In some embodiments, a catheter may include an integral detent, or other catch structure, that engages a selectively deployed latch to effect holding.

As described above, both the AGE and AID implementations described herein include a variety of port assemblies along their base in order to transmit a vacuum to the underlying tissue. As shown in FIG. **21**, an exemplary AGE **2100** includes an omega-shape body **2110** with a proximal

portion **2112** and a distal portion **2114** that each houses a catheter **2120**. A bellows-like region **2130** is provided between the proximal and distal sections **2112** and **2114**. In an AID configuration, this accordion-like bellows shape allows bending of the sections **2112** and **2114** relative to each other for guidance and steering using, for example, embedded steering wires **2140**. As shown further in FIG. **22**, the bottom side/base **2210** of the device **2100** includes a series of ports **2220**, which are shaped generally as elongated ovals in this embodiment. Alternatively the ports **2220** can be round, or any other acceptable shape. The depicted ports **2220** are disposed in a staggered arrangement along each respective base side **2230** on opposite sides of the central region **2340** that directly underlies the catheter **2120**. The base sides **2230** form outwardly-extended flanges (the bottom of the "omega") that allow the hold-down vacuum to be transmitted to the base (and hence, transmitted to the underlying tissue) over a significant surface area while still allowing the central lumen to remain largely exposed to the underlying tissue when desired without interfering ports and other structures. In this embodiment, additional side ports **2260** are also provided along the bellows region **2130** to allow to be secured to the tissue for further overall stability.

As described herein certain embodiments of the AID and AGE allow for continually opened, or selectively opened regions on the bottom, to afford direct exposure of the catheter to the underlying tissue. In other embodiments in which the bottom is substantially (or fully) closed this bottom region should be constructed from a material with high microwave transmissivity.

In an alternate AGE configuration, the distal and proximal ports can be separately accessed by independent vacuum sources to thereby allow self-ambulatory, traversing or crawling motion. Alternatively, all ports can be connected to a common vacuum source to allow hold-down of the entire device at once in an AID configuration. In a further alternate embodiment, in an AID configuration, the distal portion **2114** can be connected to a separate vacuum source so as to allow it to steer, while at least a portion of the AID (such as the proximal portion **2112**) maintains vacuum engagement with the underlying tissue. In general however (and as noted above), the various AID embodiments herein are typically implemented as a non-steering, passively applied hold-down device, which piggy-backs the microwave or other type of catheter.

IV. Actuation of Immobilizers to Effect AGE Movement

A variety of techniques can be used to actuate movement so as to generate the desired traversing motion in an AGE. These techniques can include hydraulic and pneumatic actuators, screw drives, mechanical push-pull mechanisms and electromagnetic drives. Two basic AGE pneumatic bellows actuation embodiments are shown in cross section, FIGS. **23** and **24** is now described in further detail. With reference first to FIG. **23**, the immobilizer body **2310** is shown with a cross-section taken through and interconnected bellows **2320**. This bellows **2320** is sealed against the proximal immobilizer **2340** and also against distal immobilizer (not shown) to prevent gas leaks. The proximal immobilizer channels a pair of pressure lumens **2350** into the bellows **2320**. A set of steering wires **2352** reside outside the bellows, exposed to the environment. A pair of vacuum channels **2354** also pass selectively into each of the immobilizers to control the vacuum within the central vacuum base **2356** of each immobilizer. A central lumen **2358** is provided for the catheter. By applying positive and/or negative pressure to the lumens **2350**, the bellows can be extended or contracted, respectively, allowing the proximal immobilizer **2340** to move (away or toward, respectively) relative to the distal immobilizer. While not shown, the immobilizers can be joined by a second outer sheath with a bellows-like geometry that covers the exposed steering wires and other structures, which extend between the two immobilizers. This assists in preventing the tangling or clogging of these components in bodily tissue.

The embodiment of FIG. **24** differs from that of FIG. **23** in that the steering wire lumens **2410** reside within the enclosure of the bellows **2420**. The pressure vacuum lumens **2430** provide needed pressure to expand and contract the bellows **2420**. A pair of vacuum immobilizer lumens **2450** selectively provide a vacuum hold-down force to each of the vacuum chambers **2460**. These lumens **2450** are isolated from the environment of the bellows so as to maintain a separate vacuum state for use at the vacuum chambers **2460** of the immobilizers. An internal lumen **2470** for the catheter is provided above the vacuum chamber **2460**. The steering wire lumens **2410**, must be appropriately sealed relative to the volume defined by the bellows **2420** so that vacuum pressure is not lost due to the fact that they pass through the otherwise sealed area or the bellows.

In alternate embodiments, both actuation of movement between the proximal and distal immobilizers and steering therebetween can be effected using a single force, namely pneumatic or hydraulic pressure. As shown in FIG. **25**, a distal immobilizer **2510** is provided with three independently operated bellows **2520**, **2522** and **2544**. A pair of separate vacuum lumens **2530** are also provided to impart the necessary hold-down force to the vacuum chamber **2532**. A central lumen **2540** for a catheter **2542** is also provided. By selectively actuating, with appropriate pressure and/or vacuum each of the bellows, the distal immobilizer can be moved in any direction, including forwardly at an appropriate angle, with respect to the proximal immobilizer.

FIG. **26** shows the distal end of an immobilizer **2610** that includes four bellows **2620**, **2622**, **2624** and **2626** that are arranged appropriately around the external perimeter **2628** of the immobilizer. Likewise, a catheter **2630** is provided within an appropriate lumen **2632** and a pair of vacuum lumens **2640** supply each of the vacuum chambers **2642** to provide hold-down force.

While the bellows in FIGS. **25** and **26** are circular and, generally, concentric about their appropriate vacuum lumens **2570** and **2670**, respectively, it is contemplated that the bellows can provide increased size/volume by providing them with an elongated cross-section. In FIG. **27**, the proximal immobilizer **2710** includes a pair of somewhat ovular-cross-section bellows **2720**, **2722**, **2724** and **2726** located in an efficient arrangement about the perimeter **2728** of the immobilizer **2710**. Each of these bellows is fed by an appropriate vacuum lumen **2770** that, like other bellows and lumens described herein, is in sealed communication with the proximal control system. Through use of the appropriate valves, each bellows can be selectively operated to generate a positive pressure and/or vacuum as appropriate to steer and/or advance the distal immobilizer with respect to the proximal immobilizer. A similar elongated-cross-section-bellows arrangement is shown for the immobilizer **2810** of FIG. **28**. Three bellows **2820**, **2822** and **2824**, sized appropriately, are provided about the perimeter **2828** of the immobilizer. Note that, in each of these embodiments, the lumen that transmits fluid to and from each bellows extends generally through the proximal immobilizer while the corresponding mating connection and the distal immobilizer is typically lumen-free, with the bellows simply establishing a sealed connection against the proximal end of the distal

immobilizer (not shown). In this manner fluid is either withdrawn from the bellows chamber or forced into the bellows chamber without being passed into the distal immobilizer.

One advantage to each of the above-described small-diameter, independent bellows is that they may require less total airflow/fill time to effect actuation over a given distance. This is because they collectively occupy a smaller overall volume than the larger-volume bellows described above with reference to FIGS. **23** and **24**.

An alternate type and embodiment of actuating/advancing mechanism is shown in FIGS. **29** and **30**. The depicted AGE **2910** consists of a proximal immobilizer **2920** and a distal immobilizer **2922** of a general size and shape similar to those described above. The bellows between the immobilizers **2920** and **2922** has been omitted from FIG. **29** for clarity. This bellows **3010** is shown in cross-section in FIG. **30**. As described below, the bellows **3010** is only meant to provide a compressible/expandable cover the internal components between immobilizers in this embodiment, and not to provide an actuation mechanism.

In this embodiment, the proximal immobilizer **2910** and distal immobilizer **2922** are interconnected by steering wires **2932**. These wires **2932** can be independently tensioned to allow the distal immobilizer **2922** to move angularly with respect to the proximal immobilizer **2920**. Vacuum lumens **3020** pass between the proximal immobilizer and the distal immobilizer to allow the proximal immobilizer **2920** to be selectively provided with hold-down vacuum force relative to the distal immobilizer **2922** as desired. The catheter **2930**, which spans between the proximal and distal immobilizers, is located to direct its energy downwardly through the base (**3030** in FIG. **30**).

Notably, at the top end of both the proximal and distal immobilizers is mounted an interconnecting flexible helical drive **2950**. The helical drive includes a flexible drive shaft **2952** that extends outwardly through the cannula **2954** and back to a rotating mechanism on the guidance system. The flexible helical drive screw **2950** can be constructed from any resilient acceptable polymer or flexible metal lead. In this embodiment one end of the drive **2950** is rotatably fixed, and the opposing end is allowed to rotate within a threaded nut. In this embodiment the nut **2970** is shown (in phantom) embedded in the proximal end of the distal immobilizer **2922**. As the helical drive **2950** rotates it rotates through the fixed nut, thereby moving the proximal immobilizer toward and away from the distal immobilizer. A channel **2972** (shown in phantom) is provided distally of the nut to allows run-out room for the advancing drive screw **2950** as the proximal immobilizer drives distally toward the distal immobilizer. The proximal immobilizer in this and other embodiments slides freely along any distally connected lumens, steering wires and the catheter itself **2930** so that it is free to move toward and away from the distal immobilizer. Rotation between the two immobilizers **2920** and **2922** is generally restricted as the screw **2950** rotates due to the triangular shape of the catheter **2930** and the conforming lumen **3050** (FIG. **30**). Because the catheter is somewhat flexible, it still allows the needed steering between immobilizers, however. In alternate embodiments, flexible, sliding guide rods can be used to restrict rotation of one immobilizer with respect to the other. These rods can be located separate from other connections between the immobilizers (lumens, steering wires, etc.), or the flexible anti-rotation guide rods can slidably encase some these interconnecting elements between the immobilizers (for example the steering wires).

In an alternate implementation of the helical drive screw of FIGS. **29** and **30**, both ends of the screw can include nuts, with an appropriate stop mechanism to prevent over-extension of the ends with respect to each other.

The helical drive mechanism of FIGS. **29** and **30** generally allows the distal and proximal immobilizers to be moved toward and away from each other (double arrow **2960**) based upon rotation (double curved arrow **2962**) of the shaft **2952**. Because the drive screw **2950** is flexible, it allows the steering wires **2932** to bend the distal immobilizer **2922** with respect to the proximal immobilizer **2920**, thereby affording steerability as well as linear actuation.

It is contemplated that the above-described helical drive and other helical/rotationally actuated drives described herein can be driven by a stepper, servo, or other type of motor, typically located at the proximal control system. The encoder or other motion control device can employed using the rotational or linear feedback data to provide position feedback information in connection with the immobilizer. Such information can be displayed to the user and/or used to provide automatic control functions to the actuation of the AGE.

Yet another helical-screw actuation mechanism for an AGE is shown in FIGS. **31-33**. The AGE **3110** in this embodiment includes a cannula **3112**, proximal immobilizer **3114** and distal immobilizer **3116**. The helical drive screw **3120** in this embodiment is rigid, rather than flexible. The screw **3120** engages a nut embedded in the distal immobilizer (not shown) similar to the embodiment of FIGS. **29-30** described above. Hence, the proximal immobilizer **3114** and distal immobilizer **3116** may only move toward and away from each other in a linear manner (straight double-arrow **3130**). Steering of the entire AGE in a desired direction is effected by rotating the structure about a pivoting vacuum plate **3140** located at the base of the proximal immobilizer **3114**. The vacuum plate is adapted to engage the tissue and acts as the proximal immobilizer's primary hold-down mechanism with respect to underlying tissue. When engaged with tissue, and while the distal immobilizer's vacuum is disengaged, the structure is free to rotate about an axis **3142** through the center of the vacuum plate **3140**.

A set of four steering cables **3150** are located about the perimeter of the proximal immobilizer **3114**. These steering cables **3150**, by selectively tensioning and/or releasing them, allow the proximal end to be manipulated with respect to the axis **3142**. As such, the entire AGE end (both proximal and distal immobilizers) can be moved in an appropriate direction (double curved arrow **3160**). The pivoting vacuum plate **3140** is fed by a separate vacuum line **3170** that extends back to the guidance system, and is engaged when the proximal end is held down to the tissue. Pivoting is enabled by forming a seal between the vacuum plate and end of the line **3170** that allows rotation of the plate **3140** with respect to the line end. Appropriate lip structures formed between the line and plate, and user of polymers in their construction having low-friction properties can be used to create a rotatable seal in a manner known to those of ordinary skill. Each steering cable is anchored with an anchor well **3320**, as shown in FIG. **33** near the distal face **3330** of the proximal immobilizer **3114**. Conventional vacuum lumens **3230** are provided in both the proximal immobilizer **3114** to direct appropriate vacuum pressure to the distal immobilizer **3116** so as to generate desired hold down force as needed.

Referring now to FIGS. **34-37**, another embodiment of a helical-drive-actuated AGE **3410** is shown. The AGE **3410** includes a proximal immobilizer **3412** and distal immobilizer **3414**. The helical drive **3420** is rigid in this embodi-

ment, but is secured along the distal face of the proximal immobilizer **3412** by a flexible rotating joint **3430** that interconnects with a drive shaft **3432**. As shown in the cross section of FIG. **35**, taken through the omitted outer sheath, a set of steering wires **3520** surround the perimeter and allow the distal immobilizer **3414** to steer angularly (double-curved arrow **3450**) relative to the proximal immobilizer **3412** about the flexible joint **3430**. To effect this steerable motion, the steering wires **3520** move freely through lumens in the proximal immobilizer, and are anchored in the distal immobilizer. Vacuum lumens **3530** are provided in both the proximal immobilizer, and the distal immobilizer, both being in communication with the control system, and enabling the proximal and distal immobilizers to be separately held down to the tissue by applied vacuum as desired.

With further reference to FIG. **36**, an embodiment of a flexible joint **3430** for use in the AGE of FIG. **34** is shown. This joint extends through the distal face **3610** of the proximal immobilizer from the rigid helical drive screw **3420**. In this embodiment, the nut is located within the distal immobilizer. It is contemplated in alternate embodiments that the flexible joint **3430** can be provided at the proximal face of the distal immobilizer. In that case, the nut would be provided within the proximal immobilizer. In the depicted flexible joint **3430** of FIG. **36**, the rotating, flexible components consists of a socket **3620** that engages a corresponding ball on the end of the drive shaft **3630**. Such a ball and socket arrangement allows for appropriate rotation of one member with respect to the other, at angular deflections from linear. The construction of such a ball and socket joint and should be clear to those of ordinary skill.

In an alternate embodiment of the flexible joint **3430**, shown in FIG. **37**, the end of the helical drive **3420** includes a slotted clevis **3720** that engages an overlapping universal joint base **3722** with rotating pins **3724** passing out of the base **3722** and into opposing sides of the overlapping clevis **3720**. This arrangement is similar to the universal joint found in most automobiles and its construction known to those of ordinary skill.

Another inventive type of pressure-driven AGE articulation system, according to an alternate embodiment, is shown in FIGS. **38** and **39**. The AGE **3810** consists of a proximal immobilizer **3812** and a distal immobilizer **3814** that are joined by steering cables **3820** that are configured and operate similarly to those described above. That is, the cables move freely through the proximal immobilizer **3812**, and are anchored in the distal immobilizer **3814** and tensioning of selected cables causes the distal immobilizer to point ant a non-linear (off-axis) angle with respect to the proximal immobilizer. As shown in the partial cross section in FIG. **39**, the distal immobilizer **3814** includes a rigid or semi-rigid sleeve **3920** that extends proximally toward the distal face **3922** of the proximal immobilizer **3812**. A nested sleeve **3930** extends into the overlapping sleeve **3920**. The nested, smaller diameter sleeve **3930** is open at its distal end **3934** allowing pressure and/or vacuum to fill the space within the overlapped sleeves. The outer diameter of the nested sleeve **3930** is closely matched to the inner diameter of the overlapping sleeve **3920**, or one or more sealing rings are disposed between the sleeves. In either arrangement, a relative gas seal is created between the two overlapping sleeves **3920** and **3930**. By alternately pressurizing or evacuating the lead pipe **3952**, the sleeves are moved away or toward each other, respectively.

A gap **3940** is formed in the face **3922** of the proximal immobilizer around the sleeve **3930**. This gap is sufficient to allow a degree of angular steering movement (double-curved arrow **3940**) of the sleeves **3920** and **3930** with respect to the face **3922**. In addition a flexible accordion-like bellows **3950** is provided on the lead pipe **3952** of the sleeve arrangement to allow the sleeve arrangement to pivotally bend along the bellows during steering. Hence, the distal immobilizer **3814** can pivot or steer with respect to the proximal immobilizer **3812** without binding up the two overlapping sleeves. This lead pipe, **3952** extends back to a pressure/vacuum source at the control system. These sleeves act, in essence, as a bi-directional piston. Because there is a gap **3940**, the steering cables are allowed to steer the distal immobilizer with respect to the proximal immobilizer and linear movement (double arrow **3954**) is accomplished using the sleeve arrangement.

FIG. **39**A shows an embodiment of an AGE **3960** based upon a linear actuator, which includes a proximal immobilizer **3962** and distal immobilizer **3964** that are actuated based upon an electromagnetic actuation assembly **3966**. The AGE **3960** in this embodiment includes a catheter **3968** in accordance with any of the embodiments described herein. The AGE is steered by a plurality of steering wires **3970** that extend between the proximal immobilizer **3962** and the distal immobilizer **3964**. A variety of steering mechanisms can be used in alternate embodiments, as described above. The proximal immobilizer **3962** is attached to a proximally directed cannula **3971**. The cannula extends approximately (arrow **3972**) back to the control system. It carries the electrical wires for powering the actuator, and other components used to operate the AGE movement mechanism.

The actuation assembly is shown in partial cross section in FIG. **39**B. Generally, it consists of a linear motor winding (wire coils) **3980**. The coils surround a shaft **3982** that extends between the proximal immobilizer and end point **3984** that is spaced remote from the proximal face **3986** of the distal immobilizer **3964**. A second shaft **3988** is fixed to the proximal face **3986** of the distal immobilizer **3964**. The second shaft **3988** carries magnets **3990** or another form of magnetic material. It is nested, and rides within, the larger diameter shaft **3982**. When the coils are energized with one of two respective polarities, the shafts **3982**, **3988** collectively move in each of two respective directions, depending upon the polarity. This allows the distal immobilizer **3964** to be moved toward and away from the proximal immobilizer **3962**. A flexible joint **3994** (FIG. **39**A) is provided at the proximal immobilizer. This joint **3994** can be any acceptable flexible coupling that hinges in two degrees of freedom, including a section of flexible polymer material to which the shaft **3982** is connected in the region of distal face of the proximal immobilizer **3962**. It should be clear that a variety of arrangements of linear motors consisting of magnetic members and coils that slide with respect to each other can be implemented according to alternate embodiments, within the general teachings of this embodiment.

Another inventive type of system for AGE actuation and steering is shown in FIGS. **40** and **41**. The AGE **4010** in this alternate embodiment comprises a proximal immobilizer **4012** and a distal immobilizer **4014** having any acceptable vacuum hold-down arrangement to facilitate selective engagement to underlying tissue. Alternatively, a micro-needle hold-down arrangement of a type generally described herein, or another hold-down mechanism, can be provided. The central portion **4016** of the AGE **4010** consists of pairs of disks **4020**, one of which is shown in plan view in FIG. **41**. Each of the disks **4020** opposes another disk. The number of disks **4020** is highly variable. Between the opposing disks, in one exemplary embodiment, is provided

a ring of flexible material **4030**. The flexible material **4030** provides elastic resistance to separation between the opposed disks, and limits their outward expansion and maintains rotational alignment therebetween. As discussed below in other embodiments, disks can be held in alignment and expansion can be limited using other forms of guide mechanisms.

Each disk includes a plurality of electromagnets **4110** on each of opposing faces thereof. The electromagnets are arranged so that when they are energized through wires **4050** (that extend along the cannula **4052** to the control system), the magnets in opposing disks **4020** each repel or attract each other when electrically powered, and cause the elastic material **4030** therebetween to stretch. By energizing only selected of the electromagnets around the circumference of various disk pairs, the stretch occurs differentially, causing the overall middle section **4016** to expand in a non-linear, non-axial (turning) direction. The electrical wires can be arranged to individually address certain magnets, or groups of magnets in order to obtain the appropriate degree of turn. Using known techniques, the control system can be adapted to provide variable levels of voltage or current to selected magnets.

In an alternate embodiment, the flexible material between disks is omitted and the rigid disks are contained within a cannula or tubing (or another alignment structure, such as guide wires) and move toward and away from each other under alternate activated magnetic attraction or repulsion. To conduct a flat turn in a first direction, for example, all magnets at the depicted 9 o'clock position **4150** are made to repel, while all magnets at the depicted 3 O'clock position **4152** are made to attract—and vice versa for a turn in an opposing, second direction. Climbing employs the 12 o-clock (**4154**) and 6 o'clock (**4156**) magnets. Magnets can remain aligned and maximum expansion can be limited by the guide wires, tubing, or other structures that pass through or along the disks **4020**. The number and placement of individual magnets about the perimeter is highly variable. In general the magnets should be placed so that balanced turns can be achieved using the control system provided. A control system may be adapted to provide variable power to various magnets to control the turn, or a more simplified control can employ an incremental (or simple on/off) voltage to the magnets.

It should be clear that in this, and other embodiments herein, using more conventional steering cables, that turning can occur not just along one plane, but along orthogonal planes, thereby providing the full range of point ability to the distal immobilizer. This allows it to climb and dive, as well as to move left and right.

An orifice **4130**, of appropriate size and shape is provided through the disks, and through the proximal and distal immobilizers **4012** and **4014**. This allows the therapeutic catheter **4060** to pass therethrough and reside therein. Also, as in other embodiments described herein, movement is accompanied by selective application of vacuum to each of the proximal immobilizer and distal immobilizer.

In operation, a typical movement cycle for the AGE **4010** would entail application of vacuum to the proximal immobilizer, while releasing vacuum on the distal immobilizer, causing expansion in the middle section **4016** via electrical energy, reseating, by vacuum, the distal immobilizer **4014**, and then releasing the proximal immobilizer to allow the elastic material **4030** to contract, thereby drawing the proximal immobilizer forward. Differential energizing of certain magnets causes turning during the cycle and the resulting turn is finalized by securing the distal immobilizer to the tissue by vacuum.

FIGS. **42-48** detail a variety of mechanisms that allow a proximal immobilizer and distal immobilizer to be actuated and steered with various common elements. Each mechanism will be described briefly in turn. In FIG. **42**, the proximal immobilizer **4212** and the distal immobilizer **4214** are joined by a push mechanism **4220** that passes slidably through the proximal immobilizer, across a gap **4218**, and then against the proximal face **4222** of the distal immobilizer **4214**. The push mechanism **4220** extends back to the control system and can be actuated by hand or electromechanically by the user. By pushing forward (arrow **4230**), the distal immobilizer is moved forwardly relative to the proximal immobilizer. The proximal face **4222** of the distal immobilizer **4214** includes a spherical surface that allows rotation (during steering) relative to the flattened end **4240** of the push mechanism **4220** within a limited range. The steering direction of the distal immobilizer **4214** is controlled by a plurality of steering cables **4250** that are selectively pulled (arrow **4252**) to provide steering (double-curved arrow **4260**) to the distal immobilizer **4214**.

FIG. **43** shows an embodiment of a push-pull proximal immobilizer **4312** and distal immobilizer **4314** that operate on principles similar to those described with respect to FIG. **42**. In this embodiment, the distal immobilizer includes a proximal concave well **4322** upon which the push mechanism **4320** bears. This well allows a ball shaped distal end **4340** on the push mechanism to rotatably engage the distal immobilizer **4314**. Steering cables **4350** are pulled to orient the distal immobilizer **4314** in the appropriate steering direction **4360** while the resulting ball (**4340**) and socket (**4322**) allow limited steering rotation.

FIG. **44** shows a proximal immobilizer **4412** and a distal immobilizer **4414** according to another push-pull embodiment in which a plurality of push-pull mechanisms **4420** (typically, two, three or four separate push-pull shafts) pass slidably through the proximal immobilizer **4412**, and out through the proximal control system. The distal ends **4440** of each push-pull mechanism ride in a respective concave well **4422** that allows for selective pushing and pulling (double arrows **4450**) of any of the push-pull shafts **4420** to both advance the distal immobilizer **4414**, with respect to the proximal immobilizer **4412** and angularly orient the distal end in the desired steering direction. Orientation is achieved by pushing and/or pulling one push-pull mechanism **4420** a further or lesser distance than other push-pull mechanisms. The rotation of the distal immobilizer is taken up by the rotatable engagement between the wells **4422** and distal ends **4440** of the push-pull mechanisms.

In the alternate push-pull embodiment of FIG. **45**, the proximal immobilizer **4512** and distal immobilizer **4514** are shown which a pair of linear push-pull mechanisms **4520** are controlled (double arrows **4550**) by the control system. They pass through the proximal end and allow for advancing of the distal immobilizer **4514** with respect to the proximal immobilizer **4512**. Steering is accomplished similarly to the AGE embodiment having the pivoting suction cup, as shown and described above with reference to FIGS. **31-33**. The pivoting suction cup **4560** of the present embodiment rotates both the proximal and distal immobilizers **4512** and **4514** as a joined structure based upon steering cables (not shown) that are anchored in the proximal immobilizer (similar to those of FIGS. **31-33**).

FIG. **46** details a basic embodiment of a bellows-operated AGE with a proximal immobilizer **4612** and a distal immo-

bilizer **4614** that are joined by a plurality of selectively operable bellows **4620**. Each bellows **4620** is operated by a vacuum and/or pressure source at the control system. The bellows can be inflated together to advance the distal immobilizer **4614** in a straight linear/axial direction (arrow **4630**), or the bellows **4620** can be individually operated to steer (double-curved arrow **4660**) the distal immobilizer **4614** in any desired angular direction with respect to the proximal immobilizer **4612**. Various versions of this implementation are also shown in cross-section in FIGS. **25-28**, described above.

In the exemplary embodiment of FIG. **47** a proximal immobilizer **4712** and distal immobilizer **4714** are joined by a lead screw **4720** that extends out to a manual control **4730**. The manual control allows the overall movement (arrow **4732**) of the distal immobilizer **4714** with respect to the proximal immobilizer **4712**. In this embodiment the lead screw is flexible so that movement of steering cables **4750** while steering (double-curved arrow **4760**) of the distal immobilizer **4714**. The hand-control **4730** can be substituted for a motorized control as appropriate. This arrangement is similar to that described above with reference to FIGS. **29** and **30**.

Alternatively, as shown in exemplary embodiment of FIG. **48** the proximal immobilizer **4812** and the distal immobilizer **4814** can be joined by a somewhat rigid lead screw **4820**. Note that both lead screws **4720** and **4820** typically engage a nut (not shown) embedded in the proximal end of the distal immobilizer **4714** and **4814**. In this embodiment, a flexible joint **4840** allows the lead screw **4820** and distal immobilizer **4814** to pivot together (double-curved arrow **4860**) about the joint **4840**. The distal portion of the drive shaft **4850** extends out to the control system where it engages a geared drive **4870**. Steering wires **4852** extend through the proximal immobilizer **4812** to join the distal immobilizer **4814** so that steering can be controlled by selective pulling on the steering wires **4850** at the control system end. This arrangement is similar to that shown in FIGS. **34-37**.

It should be clear that a variety of other implementations for steering and actuation can be implemented in accordance with this invention.

V. AGE and AID Steering Mechanisms

With brief reference to FIG. **49**, a basic embodiment of an AGE **4910** is shown in bottom view for further reference steering mechanisms and other operative features. It includes a proximal immobilizer **4912**, the distal immobilizer **4914** and a sealed bellows **4916** there between. The sealed bellows receives vacuum pressure through an appropriate conduit, or other lumen. One vacuum lumen **4920** communicates with the vacuum hold-down port arrangement **4922** for the proximal immobilizer **4912**. An opposing lumen **4924** passes slidably through the proximal immobilizer **4912** and communicates with a grid **4926** in the distal immobilizer. Each lumen **4920** and **4924** can be separately depressurized and/or pressurized to provide vacuum selectively to either the proximal immobilizer **4912**, the distal immobilizer **4914**, or both.

A set of steering wires (also termed "cables") **4930** (three cables in this embodiment) are disposed around the central lumen that includes the ablation catheter **4950**. The steering wires **4930** pass slidably through the proximal immobilizer **4912** and are anchored at an appropriate point in the distal immobilizer **4914**. Selective tensioning of the wires **4970** allows the distal immobilizer **4914** to point itself of the central axis **4970** in three dimensions with respect to the proximal immobilizer. The wires **4930** are each located sufficiently remote from the central axis **4970** of the device so that applying tension to one or more, while releasing tension from others induces a rotational moment about a pivot area within the central region of the bellows **4916**. In the embodiments described generally herein, the flexibility of the catheter comprises the "hinge" structure between the distal and proximal immobilizers. The catheter allows a gradual bend along the length between the immobilizers that enables multidirectional steering without binding or kinking the catheter. The degree of bending depends, in part, upon the amount of catheter length extending between the two immobilizers and the inherent bending characteristics of the catheter. This moment causes the distal immobilizer **4914** to deflect angularly with respect to the proximal immobilizer **4912**. The wires **4930** can be constructed from any strong, relative small-gauge material, including a variety of monofilament and/or braided polymers and metals.

The immobilizer in the above-described AGE **4910** uses a basic grid pattern to transmit vacuum. One advantage of a grid pattern is that it prevents excess tissue from being drawn into the vacuum chamber, which might serve to block the vacuum port and prevent effective hold-down. A possible disadvantage to a grid, on curved or bumpy tissue, is that not all grid holes may be fully covered, allowing vacuum leakage and inadvertent release of the immobilizer.

VI. Immobilization

As described above, an immobilizer can be implemented in a variety of ways. FIGS. **50-52** detail an embodiment of a vacuum immobilizer arrangement that is particularly effective on highly curved surfaces. The exemplary AGE **5010** includes a proximal immobilizer **5012** and a distal immobilizer **5014** that are steered and/or actuated by any of the mechanisms described below. On the base of each immobilizer is a suction cup **5020** and **5022**. Each suction cup comprises a plurality of respective accordion-like folds **5030** and **5032**. These allow the respective suction cup to compress as appropriate. The suction cup can be formed by any acceptable, biocompatible flexible material that maintains a semi rigid structure. The contacting base **5050** and **5052** of each suction cup can comprise a differing material if desired. Such a material should have good sealing properties and remain pliable against rough surfaces. Medical silicone is one such material.

As shown in FIG. **51** an exemplary suction cup **5020** is applied against a relatively curved tissue surface **5110**. The suction cup **5020** is then shown engaging the surface **5110** in FIG. **52**. The base area **5050** of the suction cup conforms to the shape of the tissue due to differential flexure of the accordion folds **5030**. The perimeter shape of the suction cup in this example is somewhat ovular. In alternate embodiments, the shape can be more square, circular or any other desired shape.

FIGS. **53** and **54** detail an alternate arrangement for suction cups that are applicable to either an AID or an AGE embodiment. In this embodiment, a proximal immobilizer **5312** and a distal immobilizer **5314**, joined by any conventional bellows-like or otherwise flexible central section **5316** each include a plurality of suction cups **5330**. The suction cups each comprise smaller versions of the cups **5020** and **5022** described above. In this embodiment, they are ovular, but they can be any acceptable shape. They include a plurality of folds **5340** that allow the cups to comply with the surface texture and shape of the underlying tissue. As shown more clearly in FIG. **54**, each cup includes at least one vacuum port **5410** through which vacuum communicates with the individual cups. Appropriate lumens can be provided within the structure of the immobilizers **5312** and

5314 to communicate vacuum selectively to the proximal and distal immobilizers. The cups can be constructed from the same material as the underlying immobilizer, or can be a different material that is more suited to the pliability desired in a suction cup.

As noted above, larger cups may tend to draw thereinto tissue that may serve to block a small vacuum port at the top of the cup. FIGS. **55-57** show a suction cup having an anti-vacuum choke (AVC) for that feature. The immobilizer **5510** includes an integral cup chamber **5520**. The catheter **5530** passes through the immobilizer **5510**. The large cavity of the cup may tend to draw a bolus of tissue thereinto. Since the vacuum port **5540** is relatively small, the tissue may easily block it if it is sufficiently soft and pliable. Accordingly, a pair of raised disks **5550**, or similar projecting structures, are provided as an AVC mechanism. The disks **5550** are placed relatively close to the port **5540** so that any pliable tissue drawn up by the vacuum will come to rest on the disks **5550** and a gap region **5560** will remain between the disks or bosses **5550** with any tissue bridging that gap. This gap region is sufficient for vacuum draw to be maintained around the tissue and into the adjacent cup volume **5520**.

As shown in FIG. **57**, the angle of the inner wall **5710** of a cup interior **5720** can aid in the appropriate delivery of suction and avoidance of an undesirable bolus. Also the larger the angle of this wall, the greater lateral resistance to movement and slippage, which is more critical in some procedures such as an ablation. In this embodiment, the angle AC, combined with an AVC structure **5550**, together assist in avoiding blockage of the port and cup interior by draw-in tissue. Hence, a proper vacuum can be maintained. The angle AC is between approximately 40 degrees and 90 degrees in various embodiments. However, the precise angle can be determined by applying the cup to tissue similar to that expected to be encountered within the body. Often the tissue of a pig's heart or other organ is a suitable model for human tissue of the same type.

In another embodiment, not shown, the AVC feature is a fine material mesh, generally the same size as the open face of the vacuum indent space, which is away from the roof wall of the cup in roughly the same location as the projections **5550** above, to allow the vacuum to reach all parts of the vacuum indent space. The mesh forms the front surface of a thin vacuum distribution chamber and the tissue is drawn tightly against the mesh instead of against the cup roof wall, thereby allowing for a vacuum gap.

Another embodiment of an immobilizer vacuum base structure is shown for the exemplary distal immobilizer **5812** of FIG. **58**. In this embodiment, an elongated vacuum channel **5820** is provided near the outer edges of the immobilizer **5812**. A central region **5840**, broken only by small ribs **5842** (for structural integrity and stiffness) is provided beneath the catheter lumen **5850**. In this manner, the catheter **5860** is free to emit its ablation energy (or other therapeutic properties) through the open space **5840** while substantial area for applying vacuum is afforded by the channels **5820**. The channels are fed by a vacuum lumen **5864** that passes through the central region **5870** proximally of the immobilizer **5812**. A respective pair of central vacuum chambers **5872** and **5878**, located distally and proximally of the central open space **5840** provide additional, centralized hold-down force in this embodiment. The central vacuum chambers **5872**, **5878** communicate through ports or passages (not shown) in the ribs **5874** located between the chambers **5872**, **5878** and the side vacuum channels **5820**. The channels are served by vacuum ports **5876** that communicate with the vacuum lumen **5864**. Appropriate steering cables **5880** or other actuation/steering mechanism can also be provided to interconnect with the proximal immobilizer (not shown). The proximal immobilizer can employ the same, or a similar, base structure as that depicted in FIG. **58**.

FIGS. **59-62** detail an alternate embodiment of an immobilizer that does not employ vacuum pressure to secure itself to tissue. It is recognized that small biocompatible needles and/or microneedles can be used to secure materials to pericardial tissue and other forms of body tissue without incurring pain or irreparable damage. Such microneedles can be constructed from biocompatible polymers, metals or ceramic materials. The micro needle material, for example, can be a standard biodegradable material or a biodegradable polymer, such as Polylactic Acid (PLA), Polyglycolic Acid (PGA) or others that may exhibit conductivity, which is useful as an electrical sensor in determining the effectiveness of the ablation.

As shown in FIG. **59**, an AGE **5910** of this embodiment includes a proximal immobilizer **5912** and a distal immobilizer **5914**. A catheter **5922** runs through the center of both immobilizers **5912** and **5914** and also through a bellows region **5916** that provides appropriate steering and/or actuation to the distal immobilizer **5914**. Such steering and actuation can be in accordance with any mechanism described above. In this particular embodiment, the actuation is by means of two or more bellows **5924**, which can each expand and contract individually. A pair of pressure lines **5950** and **5952** extend, respectively, to each of the proximal immobilizer **5912** and distal immobilizer **5914**.

Referring further to FIGS. **61** and **62**, within each immobilizer **5912**, **5914** is provided pairs of microneedle assemblies **5960** and **5962**. When the pressure in either line **5950** or **5952** is applied, the respective microneedle assembly **5960** and **5962** moves within a respective guideway **6110** from a retracted position as shown in FIG. **61** to an extended position as shown in FIG. **62**. In the extended position, the individual needles **6210** extend outwardly beyond the plane of the base surface **6220** of the immobilizer so that they engage the underlying tissue at an acute angle AN. In this manner, upon needle deployment/extension the immobilizer becomes essentially pinned to the tissue by large number of small needles. The number of needles on an assembly can vary both in the lengthwise direction and in widthwise direction depending on the size/diameter of the individual needles and the size of the needle assembly base **6130**. The needle assembly base **6130** can include appropriate seals or other structure that maintain a pressure seal between it and the guideway **6110**. In this manner, the needle assembly is extended by pressurizing the guideway and the needle assembly is retracted by inducing a vacuum in the guideway. Appropriate seals between the needle assemblies and the guideway prevent excessive pressure loss. To provide pressure/vacuum, each guideway **6110** can include appropriate ports **6150** in communication with a corresponding pressure lumen **5950** or **5952**.

In an alternate embodiment, a push-pull linkage can be employed, acting on each assembly of needles in communication with an externally driven linkage. Likewise, electromagnetic energy could be used in, or along the guideway **6110** to actuate each array, which includes a magnetically attracted base. In this manner, the needle bases act like solenoids responding to the force of an energized coil.

With reference to FIGS. **63-65** an alternate embodiment of a needle-based hold-down mechanism is shown. As noted above under certain conditions, the underlying tissue surface may be irregularly shaped or rounded. Accordingly, a hold-

down assembly can be constructed with a plurality of individual needle bases **6410** that are laid out in a longitudinal direction (axially with respect to the direction of extension of the AGE). Each needle base **6410** can slide upwardly and downwardly separately with respect to adjacent needle bases. In one embodiment all the needle bases reside in a common guide way **6420**, which is in communication with the pressure/vacuum source. The needle sets are collectively sealed against air leakage and allowed to independently slide along the guideway. In one embodiment, the needle sets can be covered by a highly flexible sealing membrane that, when inflated causes the needle sets to extend out of the base but prevents loss of pressure from the upper region of the guideway adjacent to the port. In another embodiment the bases have a circular shape and are each placed sealingly in a separate cylinder this selectively filled with pressure/vacuum from a common source lumen to resultantly extend retract each of the bases to a predetermined distance.

When extended, all needle bases **6410** are driven to extend out of the plane base surface **6440** of the immobilizer and into the tissue surface **6450**. Notably, as shown in FIG. **65**, because the bases **6410** are independently moveable to varying distances, the application of pressure will allow certain needle bases to extend further out (within predetermined limits that may be set by a stop) than other adjacent bases. Hence, as shown in FIG. **65**, a tissue surface **6510** that is longitudinally curved can be fully engaged. To this end, the outermost bases **6520** have extended further downwardly than the innermost bases **6540** to conform to the downwardly sloping curve of the tissue surface **6510**. The extension pressure should be chosen so that it allows differential extension of different needle sets without forcing all needle sets to extend to a maximum distance. This ensures that the unit will gently conform to the shape of the tissue without applying excessive force to it. As shown in this embodiment, a plurality of needles have been laid across both the lengthwise (longitudinal) and the widthwise directions of each set. The precise number of needles, the shape of each set base, the size of individual needles and other parameters are highly variable.

Note that in each of the above-described micro needle embodiments, one advantage is that the needles may be electrically interconnected with leads that extend back to the control system. In this manner, the needles can be used to apply energy or measure temperature or other characteristics of the tissue. This may help to determine the efficiency of the ablation process or to perform other diagnostic functions. In addition, the needles may include microscopic lumens through which medicines and other fluids can be applied to the surface. In any of the embodiments above, it is expressly contemplated that fluid conduits that provide cooling fluid or other desired gases or liquids can be included in the distal and/or proximal immobilizers or in any appropriate AID structure.

Another embodiment of an inventive hold-down mechanism is shown in FIG. **66**. In this embodiment, an AGE **6610** similar to the type shown in FIGS. **29** and **30** (although any AGE or AID can be employed herewith) is applied to the heart **6620**. The proximal cannula **6630** extends back out of the body to the control system. The AGE includes any desired steering and/or actuation mechanism such as the helical drive **6640** shown herein. On the top side of the proximal immobilizer **6612** is provided an inflatable balloon **6670**. A similar balloon can be provided on the distal immobilizer if desired. Pressure send through the cannula **6630** causes the balloon to inflate when desired. Since the heart is in close proximity to other organs or tissue **6672** within the body cavity, it is contemplated that inflation of the balloon **6670** will bring it into engagement with the tissue or organ **6672** as shown. This assists in holding down the immobilizer against underlying tissue, and may avoid the need for internal vacuum chambers, microneedles and/or other hold-down mechanisms that must engage the underlying tissue (and may block access to the catheter). Additionally, by creating and maintaining a space between the target tissue, such as the heart, and surrounding organs during ablation, the chance of injuring surrounding regions are minimized. Alternatively, this balloon **6670** can be used to supplement such mechanisms where desired.

VII. AGE Control System

Reference is now made to FIG. **67** that shows an overview of the control system for an exemplary implementation of the AGE according to an embodiment of this invention. Reference is also made to the more generalized block diagram of more generalized control system functions shown in FIG. **68**. In each diagram a microwave generator **6610** is shown. The generator is used to transmit the desired level of microwave energy to the above-described ablation catheter. Note that other forms of ablation can be employed according to this invention. Such forms of ablation include regular and light-based catheters, those that use electrical contact to cauterize tissue and cryogenic fluid-delivery systems. An appropriate energy/fluid generator for such types of catheters could be substituted for the microwave generator **6710**. In this embodiment, the microwave generator transmits energy through a line **6712** contained within the cannula of the catheter. The catheter extends through the body interface **6820** (FIG. **68**), namely skin and muscle layers covering the thoracic cavity, and into the interior of the body where the operative end of the exemplary microwave catheter **6730** resides during the procedure.

The microwave catheter **6730** is carried by the ablation guidance enhancer (the AGE **6740**) in this embodiment. The AGE. **6740** is controlled by a control system and user interface **6750** that receives air and vacuum from a source **6752** via the line assembly **6754**. This line assembly includes, typically, a separate air line **6756** and vacuum line **6757** routed from appropriate pumps within the source **6752**. Within the control system is contained a set of valves that control the hold-down function as well as (in this embodiment) the actuation function which is carried out by a bellows actuator **6760** located between the proximal immobilizer **6762** and the distal immobilizer **6764**. As shown, a proximal vacuum valve **6770** controls the hold-down of the proximal immobilizer via a proximal vacuum line **6772**. When this valve is opened, vacuum is applied to the proximal immobilizers vacuum chamber **6774**. A distal vacuum valve **6776**, also in communication with the main vacuum line **6757**, can be opened to provide a vacuum to the distal immobilizer's vacuum line **6778**. When opened, the distal immobilizer's vacuum chamber **6780** is placed under vacuum pressure allowing it to act as a hold-down.

The user coordinates (or a computer/processor automatically coordinates) the actuator's (**6760**) advance and retract valves. The advance valve **6782** and retract valve **6784** are each in communication with a separate line source **6756** and **6757**. They both communicate with the bellows actuating line **6786**. When the retract valve **6784** is opened, the vacuum source is connected with the bellows line **6786**, allowing vacuum to draw the bellows together. Typically this occurs while the distal immobilizer is held down and the proximal immobilizer is released, thereby allowing the proximal immobilizer to crawl forward. Conversely, when

the proximal immobilizer is held down, and the distal immobilizer is released, the retract valve **6784** is closed and the advance valve **6782** is opened, allowing a predetermined amount of air pressure to enter the bellows **6760**. Once the bellows is fully extended the distal immobilizer is again held down. While not shown, either within the vacuum source, or along each line, is provided appropriate pressure release and pressure monitors that prevent excessive buildup or either pressure or vacuum. Such buildup could cause failure in the device due to overstressing.

In this embodiment, a wire or cable-type steering arrangement is provided. Four cables located in quadrants around the AGE **6740** are employed. The cables are typically placed under moderate tension along the entire length of the cannula run to avoid play in the steering due to slackness. Automatic slack-removal devices, such as spring assemblies or electromechanical actuators (not shown) can be employed to maintain and regulate the desired level of tension. In this embodiment the four steering cables comprise an up cable **6790**, a down cable **6792**, a left cable **6794** and a right cable **6796**. However, in some embodiments three cables oriented at approximately 120 degree angles to each other can also be employed with appropriate mixing of control functions. Within the center of the cable arrangement is an electromechanical or mechanical joystick **6798**.

The joystick assembly is shown in further detail in FIG. **69** in accordance with one exemplary embodiment. The embodiment includes a control stick **6910** located on a ball mount, or other gimbal system **6920**. The cables **6930** are each interconnected to bases **6932** at each of four corners **6934** (or other structures) on the joystick plate **6940**. As shown the cables remain under tension and eventually neck down through a narrowed opening **6950** in the control unit to eventually comprise a tensioned cable run **6960** within the catheter assembly **6970**. Tension can be maintained by ensuring that, at no point along their run, the cables are allowed to become loose. Appropriate adjustment screws, turnbuckles and other devices can be provided to the joystick assembly to ensure that the cables remain taut and properly adjusted for center.

FIG. **70** shows a schematicized example of a control panel **7010** that can be employed in connection with AGE and in accordance with this invention. A display **7012** provides status data and other information with respect to the operation of the AGE. For example, it can provide indicators as to which hold-down is currently operating and the steering direction in which the AGE has been placed. Buttons **7020** the vacuum hold-down function of the proximal immobilizer as shown, as well as buttons **7022** that control the vacuum hold-down function of the distal immobilizer. A joystick **7030** of a type described generally in FIG. **69** for mechanically controlling the steering cables is provided at the center of the panel **7010**. Alternatively, the joystick **7030** can interface with various electomechanical, pneumatic, hydraulic or electromagnetic circuits so as to control AGEs that operate on such principals, in a manner described generally herein. A pair of slide switches **7040** and **7042** are used to advance or retract the actuator so that the immobilizer moves in a proximal direction (switch **7040**) or a distal direction (switch **7042**).

It should be clear that the control panel described herein is only exemplary, and that various hardware and software components can be used to coordinate movements of components. Likewise, the control mechanism shown herein can be provided on a computer screen, such as that available in a laptop and/or desktop PC configuration. Appropriate interfaces can be provided between the computer and its control software and the underlying mechanical components that operate the catheter. In this manner, movement of the catheter can be fully automated and largely under the control of the computer. In one example, when the user instructs the AGE to move forward by a certain amount, the computer automatically activates the hold-down vacuum in one immobilizer, advances the other immobilizer, and then activates the hold-down vacuum in the advanced immobilizer. When the user instructs a turn, the computer automatically applies an appropriate amount of steering in the desired direction to the cables or other steering devices. Electrodes within the AGE's base can indicate when a maneuver has been completed correctly.

Reference is now made to FIG. **71**, which shows an embodiment of a pressure circuit used in connection with a bellows-based actuation (and steering) system for an AGE **7110**. The AGE **7110** includes proximal immobilizer **7112** and a distal immobilizer **7114**. These immobilizers **7112**, **7114** are joined by two or more discrete bellows **7116** each communicating with its own pressure lumen **7120** and **7122**. In this embodiment, both lumens **7120**, **7122** are joined to a common pressure feed lumen at a Y-connection **7124**. However, the in another embodiment, two or more circuits of the type described in FIG. **71** can be employed together to control each respective bellows separately so as to provide steering control as well as actuation.

A pump **7130** is provided in the system. This pump delivers both pressure (arrow P) and vacuum (arrow V) simultaneously through opposite outlets **7132** and **7134**, respectively. Alternatively separate pressure and vacuum pumps can be provided at each outlet. In the depicted embodiment, each outlet **7132** and **7134** contains an appropriate two-way valve **7136** and **7138**, respectively. Either valve is closed when desired to place either pressure or vacuum into a pressure control circuit **7140**. When a valve **7136**, **7138** is open, it vents to the atmosphere via an associated vent **7142** (for vacuum) and **7144** (for pressure). Only one valve **7136**, **7138** is closed into the circuit **7140** at a time. In this example, the pressure valve **7136** is closed while the vacuum valve **7138** vents to atmosphere. A pressure regulator **7150** is provided along the pressure line **7152** of the circuit to avoid overpressure within the system. A two-way valve **7160** is provided at the feed line **7162** to the two lumens **7120** and **7122**. As shown, the valve **7160** is arranged so that the pressure line **7152** is in communication with the lumens **7120** and **7122**. In the depicted circuit **7140**, the bellows are pressurized. In an alternate position shown in the circle **7170**, the valve **7160** is rotated so that the pressure line is vented to atmosphere via the vent **7172**. The lead **7162** to the lumens **7120** and **7122** is placed in communication with the vacuum line **7176** of the circuit **7140**. In order to deliver a vacuum, the outlet valve **7138** adjacent the pump **7130** is rotated so that the vacuum outlet **7134** is placed in communication with the vacuum line **7176**. In that orientation, the lumens receive vacuum and the bellows contract.

By maintaining the valves in the appropriate positions, a continuously operating pump can deliver pressure, vacuum or neither to the bellows as desired. It should be clear but by simply duplicating the circuit **7140** and associated valves, that a plurality of bellows can be operated independently at each lumen. This alternate arrangement is expressly contemplated to provide steering as well as actuation. As described above, while AIDs are not capable of independent movement, they can be steered to place them into a desired position, once directed to an approximate location on the tissue.

VIII. Improved AID Structures

As shown in FIG. **72**, a moving-floor embodiment of an AID (or AGE) **7210** includes an outer omega-shaped/arched body **7212** with a lumen **7214** for receiving a catheter. The arch-shaped upper structure of the AID includes three cable anchors **7220** for steering cables that extend through associated lumens **7224** (shown in phantom) within the structure of the AID body **7212**. A sliding floor **7230** is provided at the base of the lumen **7214**. The sliding floor rides on ribs **7232**, which are keyed so the Omega arched structure **7212** cannot separate and dislodge the floor **7230**, face each other near the base (suction base) **7240** of the AID **7210**. In order to affect better steering, the base also includes a steering cable anchor **7250**. An associated steering cable (lumen **7252** shown in phantom) extends back through the floor. The steering cable exerts tension on the floor when steered. As the floor is pulled away, the table is drawn out with it as steering is no longer needed while the AID is immobilized. By sliding away the floor it is allows the bottom of the lumen to be exposed to the tissue so the catheter can be more closely brought into proximity with the tissue. In an alternate embodiment, an internal catheter lumen-mounted hold-down balloon or bladder can be provided—such as the balloon (**1670**) shown and described with reference to FIGS. **16** and **17**.

Reference is now made to another embodiment of an AID **7310** shown in FIGS. **73** and **74**. The AID encases a therapeutic (typically microwave-ablation) catheter **7320**, and includes a series of open hold-down segments **7330** that are separated by a predetermined distance, and are each connected by a portion of a vacuum line **7332**. The vacuum line **7332** places each segment **7330** into communication with the vacuum source, and also into communication with a more distal vacuum-line segment that transmits the vacuum along the segment line (except for the most-distal segment, which is sealed at the end). The spacing between segments **7330** is highly variable. While not shown, independent steering cables can be provided between cables to steer the unit. Alternatively, it can be steered into position using a steerable guide catheter that has been removed, allowing the segments to be held in place by vacuum. Alternate hold-down mechanisms as described above, such as the needles/microneedles or the compressing balloon can also be used with, or instead, of vacuum.

As shown further in FIG. **74**, a pair of vacuum ports **7420** are provided on the base of each segment near the respective outer edges thereof. The lumen **7430** is opened, defining a somewhat horseshoe-shape in each of the segments **7330**. This relatively open base allows the full area of the catheter to be exposed to the underlying tissue. Each segment's vacuum ports **7420** can be constructed in a variety of ways. They can be constructed as a plurality of small ports, suction cups, or any of the other types of vacuum immobilizer base structures described herein.

Another embodiment of an AID **7510** is shown in FIGS. **75-77**. In the bottom view of FIG. **75**, the AID comprises a semi-circular-cross-section (or D-shaped) housing **7520** with an internal lumen sized and arranged to receive a catheter. The elongated side bases **7530** of the AID bottom each include a series of elongated ports **7532** in communication with a vacuum lumen **7610** as shown further in FIG. **76**. A set of steering wire lumens **7620** are provided around the semi-circular portion of the housing **7520**. Associated steering wire anchors **7720** (FIG. **77**) are provided at the distal end **7722** of the AID housing **7720**. The steering wires **7620** extend proximally from these anchors, and eventually terminate at the control system. At various locations along the length of the AID bottom, a strengthening rib **7560** ties the two sides **7530** of the bottom together. This prevents the opposing elongated side bases **7530** of the AID from splaying apart along the AID's midsection. However, this ribbed bottom configuration still allows this sufficient area for the enclosed catheter to be exposed to the underlying tissue.

With reference now to FIGS. **78-80**, another embodiment of an AID **7810** is shown. This AID includes a tissue-engaging bottom with side edges **7820** and a semi-circular or D-shaped structure **7820** that defines an open lumen **7822** for receiving a therapeutic (for example, ablation) catheter. A series of openings **7830** are provided along the center of the bottom. These openings **7830** define vacuum ports **7920** that communicate with a set of lumens **7922** extending from the side edges of the structure. The ablation catheter transmits energy through the bottom wall **7940**. The wall **7940** is constructed from material having sufficient resistance, or sufficient transmissivity to microwave energy so that the energy passes efficiently into the underlying tissue. This structure has the advantage of maximizing hold-down engagement in the area of the tissue in which the microwave energy actually emits.

IX. Distal Immobilizer-Mounted Minimally Invasive Surgical Tools

While the various AGEs described herein are contemplated for use with ablation procedures, other forms of minimally invasive surgery can be undertaken using, for example, the AGE immobilization, steering and/or actuation mechanisms described herein. It is contemplated that the distal immobilizer (or the proximal immobilizer in certain embodiments) can be adapted to carry a variety of surgical tools for performing procedures other than ablation.

FIGS. **81** and **82** show an embodiment of the distal immobilizer **8110** of an AGE (or AID in some implementations) that contains a vacuum immobilizer channel **8120** according to any embodiment herein. Another type of immobilizer mechanism, such as a microneedle-based, hold-down system, can be employed in an alternate embodiment.

The exemplary immobilizer **8110** is adapted for performing biopsy procedure on internal tissues. The immobilizer **8110** includes a pneumatic, hydraulic, electromechanical or mechanically operated cutter assembly **8130** within its housing. The cutter assembly **8130** with a cutter blade **8132** that extends into a vacuum extraction port **8134** upon activation of a linkage **8136**. The cutter can be operated alternatively, by pressure and/or vacuum, a mechanical linkage or electromechanical energy, such as a solenoid. As shown in the front cross section, the dissection channel is, in fact, located along the center of the body while the two immobilizer channels **8120** are located on opposing side basis so as to remain separated from the dissection channel. Vacuum lumens **8220** are provided for each hold-down. In operation, the immobilizer is placed over an area to be separated from a drawn-in bolus of tissue, and the severed tissue is drawn into the tissue-extraction port **8134**. The blade **8132** moves forward when the tissue is in place to cut it off and draw it to the port **8134**.

Another embodiment of a distal immobilizer **8310**, which can be used in conjunction with minimally invasive surgery, is shown in FIGS. **83-84**. The distal immobilizer **8310** in this embodiment is adapted to perform tissue-dissection procedures. It also includes immobilization vacuum channels **8320** that are disposed along the sides of the base. A central vacuum tissue channel **8330** is located to extract tissue that is acted upon by a cutting knife **8340**. The knife moves downwardly (as shown in phantom in FIG. **83**) under operation of an actuator **8350**. In one embodiment, the

actuator is a pneumatic actuator. Alternatively, the actuator can be implemented as a mechanical actuator, joined by a push-pull linkage to the control system, for engagement by the user, or an electromechanical actuator such as a solenoid. The dissection knife **8340** moves downwardly below the plane of the base (as shown in phantom) to slice underlying tissue. Any detritus can then be extracted though the vacuum tissue port **8330**. This distal immobilizer **8310** is effective in any dissection operation to be performed minimally invasively.

FIGS. **85** and **86** detail another type of minimally invasive instrument constructed within a distal immobilizer **8510**. The associated vacuum immobilization, and other mechanisms, have been omitted for simplicity. Any of the above-described immobilization structures can be employed, as well as any appropriate actuation and/or steering mechanism. The instrument of this embodiment can also be used in conjunction with AID, which omits an actuation and/or steering function.

The depicted immobilizer **8510** includes a needle-guide lumen **8520** into which is mounted an elongated, flexible needle **8522** with a central lumen for delivery of fluid. The distal end **8524** of the lumen **8520** is angled at an acute angle AL with respect to the base **8526**. The angle AL can be between approximately 10 degrees and 75 degrees in an illustrative embodiment, but the angle can be highly varied in alternate embodiments. The needle **8522** is also angled to a conventional chisel point at its distal end to assist entry into tissue. The needle **8522** can be constructed from any biocompatible material including a resilient polymer or a memory metal such as Nitinol. It includes an appropriate tip **8530** for incursion into tissue **8532**. The needle **8522** communicates with a proximal fluid lumen **8540** that can be connected to a conventional fluid-introduction coupling outside the patient. Alternatively an array of microneedles could be used instead of a single needle to deliver fluids as described in the embodiment below.

Once the immobilizer **8510** is held down to the tissue **8532**, as shown in FIG. **86**, the needle can be driven forwardly (arrow **8610**) into the tissue **8532**. The bend in the needle-guide lumen **8520** causes the needle **8522**, which is constructed from flexible metal, to also bend as shown that it enters the skin at the approximate angle AL. In this manner, the needle **8522** does not pierce at a normal (perpendicular) angle to the tissue, which may cause it to puncture a thin membrane. Rather, the needle **8522** extends sideways into the tissue, with less chance of puncturing completely through an underlying membrane. In the case of the pericardium, this undesirable effect could cause a needle to puncture the heart. Once the tissue is pierced by the needle **8522**, an appropriate fluid can be delivered through the fluid lumen **8540** to exit the hollow tip **8530**.

In FIGS. **87** and **88**, another distal immobilizer **8710** is shown immobilized on tissue **8720**. The needle **8730** resides within a lumen **8732** that includes a rounded distal-most wall **8740**. The needle end **8742** is normally directed downwardly (being formed from a memory metal, or similar-property material) so that is substantially normal to the base **8750** and underlying tissue. When the needle is driven distally (arrow **8810** in FIG. **88**) the needle drives downwardly (arrow **8820** in FIG. **88**), substantially normal/perpendicular into the underlying tissue **8720** as shown. Hence, the axial, distally directed movement of the needle **8522** causes it to engage the curved wall **8740** and drive downwardly into the tissue **8720** as shown in FIG. **88**. Fluid can, thus, be delivered deeper into a tissue in this embodiment when such deeper distribution of a medicament is appropriate. A variety of other geometries and structures for allowing hypodermic needles to be deployed into tissue for delivery of medicaments or other diagnostic purposes (at an appropriate entry angle) can be employed in accordance with alternate embodiments.

As described above, rather than a single needle, an array of microneedles can be specially adapted to deliver fluid to tissue according to an alternate embodiment. This arrangement is advantageous in that is combines hold-down and fluid-delivery functions, limits over-penetration into thin-walled tissue and spreads the medicament over a wider area with better dilution so as to limit overmedication of a single point. FIG. **88**A shows a distal immobilizer **8830** that is part of an AGE having actuation and steering mechanisms in accordance with any of the above-described embodiments herein. The immobilizer **8830** includes a cavity **8832** that is adapted to store a plurality of microneedle or microspike assemblies **8834**. A vacuum or other immobilization mechanism is provided along part of the base **8836** of the immobilizer **8830**. In this embodiment, the microneedles are designed for implantation to tissue, rather than use as an immobilization mechanism. However, the teachings herein can be applied to fixed, hold-down immobilizers as described above. In other words, the electronic interconnections and fluid interconnections used in association with these immobilizers can be modified to operate with a fixed, hold-down embodiment of a microneedle array.

As shown further in FIG. **88**D, a typical microneedle assembly **8834** is further detailed. In this embodiment, the assembly **8834** includes a base **8836** that can be constructed from a biocompatible and/or biodegradable material. Biodegradable materials allow for eventual reabsorbtion of the array without need to surgically remove it when no longer needed. On the tissue-engaging bottom **8838** of the assembly **8834** is formed a microneedle or microspike arrangement **8839**. In accordance with FIG. **88**A, a driveshaft **8840** is driven distally (arrow **8842**) so that its ramped face **8844** engages an opposing ramped face **8846** on an anchoring shaft **8848** that rides within a vertical guideway **8850** that opens onto the underlying tissue **8852**. When moved distally **8842**, the engagement of the faces **8844** and **8846** causes the anchoring shaft to move downwardly (arrow **8854**) into the underlying tissue surface. **8856**. As shown, a distal-most micro needle or micro spike assembly **8860** has been deposited in the tissue surface **8856**. This, and other discrete assemblies **8834**, are stored within a chamber **8862** beneath the shaft **8840**. Each assembly includes a wire or tube **8870** that communicates through the cannula with the control system. These tubes allow delivery of electrical signals or fluid as appropriate. When the assembly **8834**, **8860** is implanted in the tissue **8856**, it remains embedded therein with its needles **8839** in engagement with the tissue surface. This interconnection allows the delivery of fluid and/or electrical signal transmission with respect to the tissue surface from a remote location at the control system. Appropriate interfaces at the control system can be employed according to those of ordinary skill for each form of interconnection. When an assembly **8860** is deposited, the next assembly in line (microneedle assembly **8872** in this example) can be moved distally (arrow **8874**) to locate it beneath the anchoring shaft **8848** for implantation. An appropriate advancing mechanism (such as a push-rod activated at the control system and extending though the cannula—not shown) can be placed behind the proximal-most assembly to drive the group of assemblies distally.

It is contemplated, that the implanting distal immobilizer (or proximal immobilizer in alternate embodiments) comes

prepackaged with the appropriate microneedle assemblies. Briefly, a fluid-delivery assembly **8880** is shown in further detail in FIG. **88**C. Beneath the assembly's housing **8882** is provided a hollow fluid reservoir region **8884**. This reservoir **8884** communicates with hollow microneedle tubules **8886** having open tips **8888**. An appropriate channel within the housing **8882** allows fluid to be transferred from the attached tube (**8870**) to the reservoir **8884**. The structure of the microneedle assembly **8880** can be fabricated in a variety of ways. For example, the microneedles can be constructed on a substrate of metal, silicon or another material using conventional photolithography processes.

A conductive, signal-transmitting microspike assembly **8890** is shown in FIG. **88**D. This structure consists of a conductive metal base **8892** that is provided within the housing **8894**. The spikes **8896** are individual segments of the metal plate **8892** that have been etched or otherwise cut into the pointed shape as shown, and then folded along their remaining connection with the metal base **8892** into the downwardly directed orientation as shown. The spikes **8896** can be cut on three sides as shown using photochemical-etching or laser-cutting techniques, among other forms of known manufacturing processes. It should be clear that a variety of manufacturing techniques and structures can be used to form either micro needles or micro spikes according to further embodiments.

In accordance with the teachings of this invention an AID or AGE can be provided with an integral ablation mechanism, or any other therapeutic device, rather than a removable catheter positioned in a conforming lumen. The distal end, for example, can include an integral ablative tip that moves across the subject tissue with any power leads that energize the tip extending through the cannula to the control system.

Reference is now made briefly to FIGS. **89-91**, which show a generalized proximal immobilizer for use with a drive helix-actuating arrangement. The proximal immobilizer **8910** includes a central vacuum chamber **8920** that communicates with vacuum lumens **9010** (FIG. **90**) a central lumen **8930** receives the catheter **9110** (FIG. **91**). Another lumen **8940**, above the central lumen **8930** receives the drive shaft **8950** (shown in phantom) and a flexible joint **8960** that resides within an enlarged chamber **8962**. The helical drive extends outwardly from the chamber on the shaft **8964** (also shown in phantom). As shown in the cross section **90**, four steering lumens **9030** are also provided around the structure. In FIG. **91**, the assembled proximal end of the immobilizer **8910** is shown with the bellows cannula flange seal **9150** in place.

FIGS. **92-95** show a distal immobilizer **9210** according to an alternate embodiment. The immobilizer includes a vacuum chamber **9220** having a plurality of vacuum ports **9222** beneath a lumen **9230** for a microwave or other catheter. Each vacuum port **9222** interconnects with a vacuum lumen **9240**. A set of steering cables are provided within steering wire lumens **9250**. In this embodiment, there are three steering wire lumens **9250**. However any appropriate number of lumens and associated wires can be employed in connection with the teachings of this invention.

An external anchor **9255** for one of the steering wires can be viewed in FIG. **92**. In this embodiment, three string cables are used, but fewer or more can be employed in alternate embodiments. Notably, another lumen **9260** is located beside the top steering cable lumen. This lumen **9260** communicates with a pressure source located at the control system. The lumen **9260** attached to a bladder or balloon **9270** located within the top of the catheter lumen **9230**. When the catheter is positioned within the lumen, the balloon **9270** can be inflated to secure the catheter in place against the bottom surface **9450** of the catheter lumen **9230**. In this manner, the distal immobilizer **9210** provides an effective hold-down mechanism for a catheter or other device inserted into a body cavity.

It should be clear that the foregoing devices provide a wide variety of mechanisms for control, immobilization, manipulation and application of a microwave ablation catheter and other therapeutic devices. It should also be clear that any of the concepts described herein can be combined with other concepts to construct further embodiments that are not expressly shown or described herein. It should also be clear that the AGE, AID and related components described herein can be constructed from a variety of commercially available materials with biocompatible characteristics where appropriate. These materials can be rigid, semi-rigid or flexible/pliable as appropriate to those of ordinary skill in designing such components. The wall thickness for various structures are highly variable and depend, in part upon the size of any lumens passing therethrough, the strength of the chosen material and the overall size/diameter of the device. Such thicknesses can be in the range of one millimeter or less, up to several millimeters. Structures can be formed using a variety of techniques including machining of stock material, molding and rapid-prototyping.

The foregoing has been a detailed description of illustrative embodiments of the invention. Various modifications and additions can be made without departing from the spirit and scope if this invention. Each of the various embodiments described above may be combined with other described embodiments in order to provide multiple features. Furthermore, while the foregoing describes a number of separate embodiments of the apparatus and method of the present invention, what has been described herein is merely illustrative of the application of the principles of the present invention. For example, the materials employed for the various components herein are highly variable, and can be combined in many ways to provide appropriate characteristics adapted to the particular therapeutic goal. The shape and size of a contained catheter can be highly variable, and the AID or AGE can include a lumen particularly sized and shaped to accommodate the catheter. The external perimeter shape of the AID or AGE can be adapted to the desired delivery system, including a trocar, guiding catheter or guidewire. Also, these devices herein can be fitted with a variety of devices and sensors for measuring characteristics of the contacted tissue and body cavity including, but not limited to heart sensors, temperature sensors and miniature (fiber optic) cameras, which can be placed in conjunction with the catheter or surgical tool to provide appropriate readings of the surrounding area. Also, it is expressly contemplated that any of the devices described herein can be adapted to be employed on any internal organ or tissue structure. Variations in size, shape and other characteristics needed to adapt a device to such a task should be apparent to those of ordinary skill. Likewise the introduction system and location can be adapted to reach such an organ or internal location using techniques known to those of ordinary skill. Accordingly, this description is meant to be taken only by way of example, and not to otherwise limit the scope of this invention.

What is claimed is:

1. A method for ablating a target tissue in a patient's body, the method comprising:

providing a device comprising an ablation catheter comprising an ablation element; and

an immobilizer mechanism coupled to the ablation catheter, wherein the immobilizer mechanism is distal to the ablation element, is configured to anchor the catheter and to axially pull the ablation element toward the immobilizer mechanism after the immobilizer mechanism is engaged;

inserting the device into a patient's body;

immobilizing the device within the patient's body;

axially pulling, via the immobilizer mechanism, the ablation element to contact to a target tissue while the immobilizer mechanism is engaged; and

ablating a surface of the target tissue.

2. The method according to claim **1**, wherein the target tissue is cardiac tissue.

3. The method according to claim **1**, wherein the ablation catheter is a radiofrequency ablation catheter.

4. The method according to claim **1**, wherein the device is steerable.

5. The method according to claim **1**, wherein the immobilizer mechanism comprises an electrical conductivity sensor.

6. The method according to claim **5**, wherein the electrical conductivity sensor can verify that a therapeutic ablation has been delivered.

7. The method according to claim **1**, further comprising a locking mechanism that is configured to lock the ablation catheter axially in place.

8. The method according to claim **1**, wherein the device further comprises a control system operably coupled to the device.

9. The method according to claim **8**, wherein the control system controls an amount of energy transmitted to the ablation catheter.

10. The method according to claim **7**, wherein when the locking mechanism is engaged, the ablation element maintains contact with the target tissue during ablation.

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